

**SAFETY OF THE U.S. FOOD SUPPLY: CONTINUING
CONCERNS OVER THE FOOD AND DRUG AD-
MINISTRATION'S FOOD-RECALL PROCESS**

HEARING
BEFORE THE
SUBCOMMITTEE ON OVERSIGHT AND
INVESTIGATIONS
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED FIFTEENTH CONGRESS
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C O N T E N T S

	Page
Hon. Gregg Harper, a Representative in Congress from the State of Mississippi, opening statement	1
Prepared statement	3
Hon. Diana DeGette, a Representative in Congress from the State of Colorado, opening statement	4
Hon. Greg Walden, a Representative in Congress from the State of Oregon, opening statement	6
Prepared statement	7
Hon. Frank Pallone, Jr., a Representative in Congress from the State of New Jersey, opening statement	8
Prepared statement	9
Hon. Michael C. Burgess, a Representative in Congress from the State of Texas, prepared statement	49

WITNESSES

Gloria L. Jarman, Deputy Inspector General for Audit Services, Office of Inspector General, Department of Health and Human Services	11
Prepared statement	13
Answers to submitted questions	
Douglas W. Stearn, Acting Deputy Director for Regulatory Affairs, Center for Food Safety and Applied Nutrition, and Director, Office of Enforcement and Import Operations, Office of Regulatory Affairs, Food and Drug Administration, Department of Health and Human Services	23
Prepared statement	25
Answers to submitted questions ¹	62

SUBMITTED MATERIAL

Subcommittee memorandum	50
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¹ Mr. Stearn did not answer submitted questions for the record by the time of printing.

SAFETY OF THE U.S. FOOD SUPPLY: CONTINUING CONCERNS OVER THE FOOD AND DRUG ADMINISTRATION'S FOOD-RECALL PROCESS

FRIDAY, JANUARY 19, 2018

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:00 a.m., in room 2123, Rayburn House Office Building, Hon. Gregg Harper (chairman of the subcommittee) presiding.

Members present: Representatives Harper, Griffith, Brooks, Collins, Walberg, Costello, Carter, Walden (ex officio), DeGette, Schakowsky, Castor, Tonko, and Pallone (ex officio).

Staff present: Jennifer Barblan, Chief Counsel, Oversight and Investigations; Ray Baum, Staff Director; Jordan Davis, Director of Policy and External Affairs; Ali Fulling Legislative Clerk, Oversight and Investigations, Digital Commerce and Consumer Protection; Brittany Havens, Professional Staff Member, Oversight and Investigations; Jennifer Sherman, Press Secretary; Alan Slobodin, Chief Investigative Counsel, Oversight and Investigations; Jacquelyn Bolen, Minority Professional Staff Member; Evan Gilbert, Minority Press Assistant; Christopher Knauer, Minority Oversight Staff Director; Miles Lichtman, Minority Policy Analyst; Kevin McAloon, Minority Professional Staff Member; Tim Robinson, Minority Chief Counsel; and Andrew Souvall, Minority Director of Communications, Member Services, and Outreach.

OPENING STATEMENT OF HON. GREGG HARPER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MISSISSIPPI

Mr. HARPER. The subcommittee convenes this hearing entitled "Safety of the U.S. Food Supply: Continuing Concerns Over the Food and Drug Administration's Food-Recall Process." Disease outbreaks from tainted food are an ongoing public health challenge. The Centers for Disease Control estimates that each year, one in six Americans, 48 million people, get sick from foodborne illnesses, 128,000 are hospitalized, and 3,000 die.

The number of multistate food illness outbreaks is increasing, affecting greater numbers of Americans. And the number of vulnerable people, older and immune-compromised individuals, is growing. The threat of foodborne illness persists even though we have

gotten better at detecting and investigating outbreaks. And through the implementation of the Hazard Analysis and Critical Control Point rules over the last two decades, CDC trend data indicates major reductions in the incidents of foodborne disease. Yet the problem remains significant.

When contaminated food reaches store shelves, the FDA is a public's last line of defense. The FDA needs to be able to quickly and effectively help remove dangerous foods from commerce and protect consumers. In 2010, Congress gave FDA more power to recall tainted food. The FDA Food Safety Modernization Act, FSMA, was enacted to provide FDA with the authority to mandate a food recall.

In addition to this law, previous audits by both the HHS, Office of Inspector General, and the Government Accountability Office made recommendations to FDA to improve its food-recall program. How has FDA performed with food recalls in recent years with the new law and these recommendations? Over the last 2 years, the HHS OIG looked at this question, and last month released a report that contains findings and recommendations for FDA.

The OIG report looked at 30 voluntary food recalls overseen by FDA between October of 2012 and May of 2015. The FDA has used its mandatory recall authority only two times since the enactment of FSMA, and not at all over the last 4 years. In some cases, the FDA was slow to evaluate health hazards. It took FDA an average of 47 days to complete an evaluation after learning of a planned or in-progress food recall.

The OIG found that FDA was woefully slow in starting recalls. The average length before a recall began, once FDA knew of the safety issue, was 57 days. The report also raises questions about the FDA's ability to cope with uncooperative companies.

In one case involving a dietary supplement company, it took 10 months after FDA issued a warning letter about unlisted ingredients before the firm finally pulled the product. In another case, a recall of nut butter began more than 5 months after the FDA had traced the Salmonella outbreak to the source facility. There were 14 illnesses in 11 States during that time.

A series of recalls of cheese products contaminated with *Listeria* took 81 days to complete, nine people got sick, including one infant who died, and two fetal losses linked to illness. During that time, the firm owner lied to the FDA, saying that the firm would suspend the manufacturing and distribution of cheese. However, the owner, despite knowing that the product tested positive for *Listeria*, continued to allow the product to be distributed. The owner later pleaded guilty to FDA crimes and went to prison. Justice was done, but FDA needed to find a way to detect such deception sooner.

The OIG also found that FDA did not have a reliable system for accessing the recall initiation date, or the date FDA became aware of potentially hazardous food products. More than a third of the recalls reviewed had the wrong initiation date entered into FDA's electronic data system, called the Recall Enterprise System.

The electronic data system also did not include when FDA first found out about the suspect food products. Worse, FDA does not collect sufficient or accurate data so that the agency can measure

its performance to tell whether their food-recall performance is improving.

In addition to the OIG findings, the FDA told committee staff in a briefing that there are concerns about the turn-around time it takes to get test results from FDA labs that are used to make an evaluation of the seriousness of the food hazard.

To ensure the FDA labs are performing properly, FDA needs to provide independent funding and permanent staff to its Office of Laboratory Science and Safety. This office has not been fully stood up and has been unable to inspect FDA labs. FDA should follow the example of the CDC. The CDC's Office of Lab Science and Safety has dedicated funding and permanent staff to oversee CDC's own labs.

The enactment of FSMA provided FDA mandatory recall authority and imposed more legal obligations on food manufacturers and distributors. FDA has the tools, but the OIG's findings and FDA's own assessments, show that the FDA needs to reform itself to get this right. I'm heartened that the FDA commissioner has recognized that even just a handful of problematic recalls are too many, because lives are at stake.

I'm also glad that the Commissioner has announced that FDA is looking at ways to improve the timeliness and scope of information provided to the public about FDA-regulated food recalls.

I welcome and thank the witnesses and look forward to their testimony.

[The prepared statement of Mr. Harper follows:]

PREPARED STATEMENT OF HON. GREGG HARPER

The subcommittee convenes this hearing entitled "Safety of the U.S. Food Supply: Continuing Concerns Over the Food and Drug Administration's Food-Recall Process."

Disease outbreaks from tainted food are an ongoing public health challenge. The Centers for Disease Control (CDC) estimates that each year one in six Americans—48 million people—get sick from foodborne illness, 128,000 are hospitalized, and 3,000 die. The number of multistate food illness outbreaks is increasing, affecting greater numbers of Americans. And the number of vulnerable people, older and immune-compromised individuals, is growing.

The threat of foodborne illness persists, even though we have gotten better at detecting and investigating outbreaks. And through the implementation of the Hazard Analysis and Critical Control Point (HACCP) rules over the last two decades, CDC trend data indicates major reductions in the incidence of foodborne disease. Yet the problem remains significant.

When contaminated food reaches store shelves, the FDA is the public's last line of defense. The FDA needs to be able to quickly and effectively help remove dangerous foods from commerce and protect consumers. In 2010, Congress gave FDA more power to recall tainted food. The FDA Food Safety Modernization Act (FSMA) was enacted to provide FDA with the authority to mandate a food recall. In addition to this law, previous audits by both the HHS Office of Inspector General (OIG) and the Government Accountability Office (GAO) made recommendations to FDA to improve its food-recall program.

How has FDA performed with food recalls in recent years with the new law and these recommendations? Over the last 2 years, the HHS OIG looked at this question and last month released a report that contains findings and recommendations for FDA.

The OIG report looked at 30 voluntary food recalls overseen by FDA between October 2012 and May 2015. The FDA has used its mandatory recall authority only two times since the enactment of FSMA and not at all over the last 4 years. In some cases, the FDA was slow to evaluate health hazards. It took FDA an average of 47 days to complete an evaluation after learning of a planned or in-progress food recall.

The OIG found that FDA was woefully slow in starting recalls. The average length before a recall began once FDA knew of the safety issue was 57 days.

The report also raises questions about the FDA's ability to cope with uncooperative companies. In one case involving a dietary supplement company, it took 10 months after FDA issued a warning letter about unlisted ingredients before the firm finally pulled the product. In another case, a recall of nut butter began more than 5 months after the FDA had traced the Salmonella outbreak to the source facility. There were 14 illnesses in 11 States during that time.

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The OIG also found that FDA did not have a reliable system for accessing the recall initiation date or the date FDA became aware of potentially hazardous food products. More than a third of the recalls reviewed had the wrong initiation date entered into FDA's electronic data system, called the Recall Enterprise System (RES). The electronic data system also did not include when FDA first found out about the suspect food products. Worse, FDA does not collect sufficient or accurate data so that the agency can measure its performance to tell whether their food-recall performance is improving.

In addition to the OIG findings, FDA told committee staff in a briefing that there are concerns about the turnaround time it takes to get test results from FDA labs that are used to make an evaluation of the seriousness of the food hazard. To ensure the FDA labs are performing properly, FDA needs to provide independent funding and permanent staff to its Office of Laboratory Science and Safety. This office has not been fully stood up and has been unable to inspect FDA labs. FDA should follow the example of the CDC. The CDC's Office of Lab Science and Safety has dedicated funding and permanent staff to overseeing CDC's own labs.

The enactment of the FSMA provided FDA mandatory recall authority and imposed more legal obligations on food manufacturers and distributors. FDA has the tools, but the OIG's findings and FDA's own assessments show that the FDA needs to reform itself to get this right.

I am heartened that the FDA Commissioner has recognized that even just a handful of problematic recalls are too many, because lives are at stake. I am also glad that the Commissioner has announced that FDA is looking at ways to improve the timeliness and scope of information provided to the public about FDA-regulated food-recalls.

I welcome and thank the witnesses, and look forward to their testimony.

Mr. HARPER. I'll now recognize the ranking member, Ms. DeGette, for the purpose of her opening statement.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you so much, Mr. Chairman. As you know, food safety is not a new issue for this committee. Many of the challenges that we're going to hear about today are the same issues that we've dealt with over the past decade. All of those examples you mentioned were brought up in hearings in front of this committee.

For example, we held a hearing in 2008 on a major Salmonella outbreak that infected over 1,300 people in 43 States. As that case illustrated, we lacked basic controls over food recalls, including traceability. FDA and CDC originally identified tomatoes as the likely cause of the outbreak, but later on they found out it was because of jalapenos.

Now, this was frustrating to all of us because lives were at stake. The Federal response was slow and inefficient, and yet that case

demonstrated that the response is not as simple as just pulling off all the suspected products from the shelves, because an entire industry should be devastated.

When we had these hearings where we thought it was the tomatoes, the tomato industry was absolutely devastated at that time, and it turned out that the problem wasn't even tomatoes, but jalapenos. So it was clear then, as it is now, that the FDA needs the ability to respond to a multitude of different situations that pose risks to the public health.

As you noted, Mr. Chairman, in response to incidents like that, we passed the FDA Food Safety Modernization Act in 2011, and many of the Members on this committee worked in a bipartisan way on that bill. It gave the FDA more tools to prevent and to respond to outbreaks, including, critically, new authority to issue mandatory recall orders and requirements for manufacturing firms to have recall plans in place.

But now, 7 years after we pass the law, the Office of Inspector General has a new report that points to some of the same issues that we've been worrying about in this committee for years. Despite the progress that we've made, here we find ourselves.

OIG found that, despite more power to oversee manufacturing firms that produce potentially hazardous food, FDA is not doing enough to monitor firms during a recall. Sometimes there have been long delays in getting firms to recall all of their affected product, or even to provide the FDA with basic information.

In addition to insufficient oversight of firms, FDA has also weaknesses in its own recall responses. For example, it's critical for the public to understand the risk that a food product may present. But OIG found that FDA was sometimes slow to evaluate the health hazard posed by a contaminated product.

This is not to say that these cases are easy and the answer's always crystal clear. The FDA is dealing with many recalls every year, each of which presents its own challenges and complexities. That being said, I do think there's more the FDA can do to improve the food safety system.

OIG's report presents multiple recommendations for FDA, such as improving its policies and procedures for managing recalls and monitoring firms. However, I'd like to hear more from OIG about what specific meaningful steps it thinks FDA should take. A few more procedure documents and guidance manuals are not enough. We need to know what actually needs to change to help better protect the American public.

As FDA continues to implement provisions of FSMA, the committee needs to hear how the law is working, what more the FDA needs to do, and how Congress can help. I'd like to take a moment of personal privilege, if I may. I just saw the former chairman of the committee walk into the room, Bart Stupak, and Congressman Stupak was one of the key players in enactment of this food safety legislation. Welcome. We're glad to have here you. I'm sorry that we're still talking about this 7 years later.

With that, Mr. Chairman, I yield back.

Mr. HARPER. The gentlelady yields back. And I would also like to welcome Mr. Stupak for his attendance today. It's great to see you back, and wish you the best. Now the Chair would recognize

the chairman of the full committee, Mr. Walden, for the purpose of an opening statement.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. Thank you, Mr. Chairman. And, Bart, good to see you again. I enjoyed serving with you when we did all that oversight work, and it's good to see you here.

You know, I take this issue very personally. In February of 2009, this subcommittee held hearings on nationwide outbreaks of Salmonella-related illnesses linked to products from the Peanut Corporation of America. One of the witnesses at that hearing was Peter Hurley from Wilsonville, Oregon.

When Peter's then 3-year-old son, Jake, became sick, doctors recommended they give him his favorite food just to encourage him to eat. Well, Jake's favorite food was Austin brand peanut butter crackers. Tragically, that turned out to be the very thing that was poisoning him. When Oregon State officials tested the crackers, three of the six packages contained peanut butter contaminated by Salmonella.

Jake became ill because Stewart Parnell, the CEO of PCA, knew that the peanut products were contaminated with Salmonella when he told the plant manufacturer to, quote, "turn them loose." At that same hearing, I confronted Mr. Parnell with this container, and I asked him whether he was willing to take the lid off and eat any of these products now, since he was so cavalier about turning it loose on little kids like Jake to eat. He refused, of course, citing his 5th Amendment rights.

Thankfully, Jake overcame his illness, and it was great to see him last year. He's now a young teenager. He and his dad came back to visit us. More than 600 people in 44 States were sickened. And, unlike Jake, nine people died. As a result, Mr. Parnell is currently serving a 28-year sentence in prison for his actions.

Now, while this case of PCA is the exception and not the rule, fortunately, foodborne illnesses remain a major concern. Chairman Harper just ran through those numbers. Each year, 48 million people are sick and 3,000 die from foodborne illnesses. Federal oversight of food safety has been on the Government Accountability Office's high-risk list since 2007.

And just in the past few months, dozens of people in the United States and Canada were infected and two have died from what appears to be an E. coli contamination related to leafy greens. So we're here today to check in on the Food and Drug Administration and their work to protect the Nation's food supply chain and ensure health and safety for all Americans.

I was glad to see the FDA Commissioner, Scott Gottlieb, showed his commitment to improving food safety in our Nation with yesterday's announcement that the FDA will accelerate the release of information about problematic products before they may officially be classified as recall items. We look forward to hearing from the FDA today about what plans and benchmarks it's developed to fully implement the law and address the recommendations from the OIG.

We also look forward to the FDA implementing the other expert recommendations to provide proper funding and permanent staff to

the FDA office that oversees the FDA labs, which do play a critical role in food recalls.

I thank the HHS OIG for testifying today and commend its work with both the recent report in December as well as the Early Alert it issued to FDA in June of 2016. This recent work builds on the past work done by the OIG, most notably two reports related to food recalls that were released in 2009 and 2011.

While the reports from 2009 and 2011 were issued prior to the Food Safety Modernization Act, many of the recommendations in the recent December report are similar, if not the same as they were in 2009 and 2011.

Further, the GAO raised concerns about FDA's food-recall process in 2012. And while FDA says that it's addressed many of the findings of the recent OIG report, it is troubling that many of the recommendations from almost a decade ago stand today, despite the additional authority given to the FDA through FSMA in 2010.

Today's hearing will give us a good opportunity for FDA to share specific plans to address the recommendations made by the OIG, including the timeframe in which we can expect these changes to be implemented. I don't see Dr. Burgess, I know he was looking for some time. If anyone else would like the remainder of my time—if not, I will yield back to the chairman so we can proceed with the hearing.

And I also have another hearing I have to go to, so I'll be in and out of this one. Thank you again for the good work you do. I know we're on the same team to try to and make sure Americans can trust their food is safe to eat. With that, I yield back.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Thank you, Mr. Chairman, for holding this important hearing.

I take this issue very personally. In February 2009, this subcommittee held a hearing on the nationwide outbreak of Salmonella-related illnesses linked to products from the Peanut Corporation of America (PCA). One of the witnesses at that hearing was Peter Hurley, from Wilsonville, Oregon. When Peter's then 3-year-old son, Jake, became sick, doctors recommended that they give him his favorite foods to encourage him to eat. Well, Jake's favorite food was Austin brand peanut butter crackers—which turned out to be the very thing that was poisoning him. When Oregon State officials tested the crackers, three of the six packages contained peanut butter contaminated by Salmonella.

Jake became ill because Stewart Parnell, the CEO of PCA, knew that the peanut products were contaminated with Salmonella when he told the plant manager to "Turn them loose." At that same hearing, I confronted Mr. Parnell with this container of products. I asked him whether he would be willing to take the lid off and eat any of these products now, since he was so cavalier about turning it loose on little kids like Jake. He declined to answer, citing the Fifth Amendment.

Thankfully, Jake overcame his illness, and it was great to see him, now a young teenager, and his dad during a visit to DC last year. More than 600 other people in 44 States were sickened. Nine people died. As a result, Mr. Parnell is currently serving a 28-year sentence for his action.

While the case of PCA is the exception, and not the rule, foodborne illness remains a major concern. Chairman Harper just ran through the numbers—each year 48 million people become sick and 3,000 die from foodborne diseases. Federal oversight of food safety has been on the Government Accountability Office's high-risk list since 2007.

And just in the past few months, dozens of people in the United States and Canada have been infected and two have died from what appears to be *E. coli*-contaminated leafy greens. We are here today to check in on the Food and Drug Administra-

tion (FDA) and their work to protect the Nation's food supply chain and ensure the health and safety of Americans.

I was glad to see that FDA Commissioner Gottlieb showed his commitment to improving food safety in our Nation with yesterday's announcement that the FDA will accelerate the release of information about problematic products before they may officially be classified as recalled items. We look forward to hearing from FDA today about what plans and benchmarks it has developed to fully implement the law and address the recommendations from the OIG. We also look forward to FDA implementing other expert recommendations to provide proper funding and permanent staff to the FDA office that oversees the FDA labs, which play a critical role in food recalls.

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While the reports from 2009 and 2011 were issued prior to the Food Safety Modernization Act (FSMA), many of the recommendations in the recent December report are similar, if not the same, as they were in the 2009 and 2011 reports. Further, the GAO also raised concerns about FDA's food-recall process in 2012. While FDA says that it has addressed many of the findings in the recent OIG report, it is troubling that many of the recommendations from almost a decade ago stand today despite the additional authority given to the FDA through FSMA in 2010.

Today's hearing will be a great opportunity for FDA to share specific plans to address the recommendations made by the OIG, including the timeframe in which we can expect these changes to be implemented.

I welcome our witnesses and look forward to their testimony.

Mr. HARPER. Thank you, Mr. Chairman. Now the Chair will recognize the ranking member of the full committee, Mr. Pallone, for purposes of an opening statement.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman. This committee has a long history of overseeing food safety. Over the last decade, we've had multiple hearings examining the Food and Drug Administration's oversight of food recalls and the agency's authority to protect the Nation's food supply.

FDA plays a critical role. In fiscal year 2017 alone, FDA oversaw more than 3,600 recalls, and this is no small task, but we have seen cases that exposed weaknesses in FDA's ability to respond to these threats. For example, as already mentioned, in 2007 a committee investigation into a Salmonella outbreak identified serious flaws in our food safety network.

In 2010, the committee found that FDA had limited authority to ensure compliance and did not always take swift action when needed. Witnesses repeatedly told this committee that FDA lacked sufficient authority to address weaknesses in our food safety system, and that's why Congress passed the FDA Food Safety Modernization Act, or FSMA, in 2011, and FSMA significantly reformed FDA's overall approach to food safety and gave FDA new authorities to strengthen the food-recall process.

For instance, FDA now has the ability to mandate recall when a product poses a serious adverse health consequence. This is a significant tool because we've seen cases of manufacturing firms reluctant to cooperate with the FDA. And thanks to FSMA, firms are also now required to have recall plans in place to help prepare before contamination occurs.

FSMA provided these new tools, but it's up to FDA to make sure they are being put to good use, and that's why this hearing is so important. We need to hear about how FDA is implementing FSMA, and whether things have improved since we passed the law. A recent Office of Inspector General report shed some light on that question and suggests that FDA still may not always adequately oversee food recalls.

The Inspector General reported that FDA did not always effectively monitor firms during a recall, such as ensuring that firms initiate the recalls promptly. And some of the cases highlighted in the report are particularly troubling. For example, between 2012 and 2014, as was mentioned, nut butter contaminated with *Salmonella* sickened 14 people in 11 States. FDA identified the source of the outbreak in March of 2014, but the products were not fully recalled until August of that year, 165 days later.

The Inspector General also cited a series of recalls of cheese products that were contaminated with *Listeria* and led to one infant's death and two lost pregnancies. And I know everyone on this committee will argue that even one fatality is far too many. So, while we should recognize that these issues are complex and every recall poses a unique challenge, these findings demonstrate that FDA must exercise judicious yet forceful oversight when the public's health is at risk.

And so I look forward to hearing how FDA is implementing FSMA and what challenges remain to protect our Nation's food supply. I don't think anyone else wants my time, so I'll yield back, Mr. Chairman.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

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I look forward to hearing how FDA is implementing FSMA and what challenges remain to protect our Nation's food supply.

I yield back.

Mr. HARPER. The gentleman yields back. I ask unanimous consent that the Members' written opening statements be made part of the record. And, without objection, they will be entered into the record.

I'd now like to introduce our panel of witnesses for today's hearing. Today we have Ms. Gloria Jarmon, who is the Deputy Inspector General of Audit Services for the Office of Inspector General at HHS. We welcome you today. And Mr. Douglas Stearn, the Director of the Office of Enforcement and Import Operations in the Office of Regulatory Affairs at the FDA. Welcome to you both, and thank you for being here today to help and to provide testimony. And we look forward to the opportunity to discuss the FDA's food-recall process.

You are aware that the committee is holding an investigative hearing, and when so doing, it has the practice of taking testimony under oath. Do you have any objection to testifying under oath?

Mr. STEARN. No, sir.

Ms. JARMON. [No verbal response.]

Mr. HARPER. Both witnesses have indicated no. The Chair then advises you that, under the rules of the House and the rules of the committee, you're entitled to be accompanied by counsel. Do you desire to be accompanied by counsel during your testimony today?

Mr. STEARN. No, sir.

Ms. JARMON. [No verbal response.]

Mr. HARPER. Both witnesses have indicated no. In that case, if you would, please rise and raise your right hand, and I will swear you in.

Do you swear that the testimony you're about to give is the truth, the whole truth, and nothing but the truth?

Mr. STEARN. I do.

Ms. JARMON. I do.

Mr. HARPER. Thank you. And you may both be seated. You're now under oath and subject to the penalties set forth in Title 18, Section 1001 of the United States Code. You may now give a 5-minute summary of your written testimony. And we will recognize Ms. Jarmon first for your testimony.

STATEMENTS OF GLORIA L. JARMON, DEPUTY INSPECTOR GENERAL FOR AUDIT SERVICES, OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES, AND DOUGLAS W. STEARN, ACTING DEPUTY DIRECTOR FOR REGULATORY AFFAIRS, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, AND DIRECTOR, OFFICE OF ENFORCEMENT AND IMPORT OPERATIONS, OFFICE OF REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

STATEMENT OF GLORIA L. JARMON

Ms. JARMON. Good morning, Chairman Harper, Ranking Member DeGette, and other members of the subcommittee. I am Gloria Jarmon, Deputy Inspector General, Audit Services, Office of Inspector General, U.S. Department of Health and Human Services. I appreciate the opportunity to appear before you today.

Conducting audits, evaluations, and inspections aimed at food safety is a priority for OIG and remains key to our mission of protecting the health and safety of the American people. I'm here today to discuss our recently published audit report on the food-recall process at the Food and Drug Administration and our recommendations for improving that process.

This audit reviewed documentation for 30 recalls, which were judgmentally selected from the 1,557 food recalls reported to FDA between October 2012 and May 4, 2015. For the 30 recalls we reviewed, we found that FDA's food-recall process was not always effective and efficient in ensuring the Nation's food supply. Specifically, we identified deficiencies in FDA's oversight of recall initiation, FDA's monitoring of recalls, and the recall information captured and maintained in the FDA's recall data system.

My testimony today focuses on key aspects of these three findings and OIG's recommendations to FDA for improving its food-recall process. First, our review of FDA's oversight of firm initiator recalls determined that FDA cannot always ensure that firms initiated recalls promptly and did not always evaluate health hazards in a timely manner.

To improve FDA's oversight of recall initiation, we recommended that FDA establish set internal timeframes for discussing the possibility of a voluntary recall with a firm and initiating the use of its mandatory recall authority. In addition, we recommended that FDA take several specific actions aimed at ensuring that health hazard evaluations are completed in a timely manner.

Second, our audit also identifies several deficiencies in FDA's monitoring of firm initiator recalls. Specifically, we found that FDA did not always issue audit checks at the appropriate level, complete audit checks as assigned, and collect timely and complete status reports from recalling firms. To improve FDA's monitoring of recalls, we recommended that FDA take steps to ensure that audit checks are assigned at the level specified in the audit program and that product distribution lists are complete and accurate.

It takes specific actions to help ensure that audit checks are completed in a timely manner and implement procedures for requesting status reports of initiation of a recall and follow up with firms that do not provide timely or complete status reports.

Third, our review of FDA's recall data system determined that FDA did not always track key recall data and maintain accurate recall data. To help ensure the completeness and accuracy of data in the data systems and give FDA staff involved in managing recalls access to information about key events, we recommended, among other things, that FDA consider adding to its recall data system, or another FDA system, a field for the date FDA learns of a potentially hazardous product, and clarify the definition of recall initiation date in its policies and procedures, and ensure a consistent understanding of recall initiation date among recall personnel.

In FDA's comments on our report, it agreed with our conclusion that it needs to help ensure that recalls are initiated promptly in all circumstances. FDA said it will continue to consider the results of our audit as it moves forward to operate its SCORE team, which stands for Strategic Coordinated Oversight of Recall Execution. This SCORE initiative was developed to establish set timeframes, expedite decision making to recall cases forward, and improve electronic recall data.

We appreciate the steps that FDA has taken, as well as the steps it plans to take, to address the vulnerabilities we identified during our audit. OIG work has demonstrated ways for FDA to improve its oversight of the food-recall process, and we will continue to work with the FDA and Congress to help ensure the safety of the Nation's food supply.

Again, thank you for the opportunity to testify this morning, and I'm happy to answer your questions.

[The prepared statement of Ms. Jarmon follows:]



**Testimony Before the United States House of Representatives
Committee on Energy and Commerce
*Subcommittee on Oversight and Investigations***

**Safety of the U.S. Food Supply: Continuing Concerns Over the Food and
Drug Administration's Food-Recall Process**

Testimony of:

Gloria L. Jarmon
Deputy Inspector General for Audit Services
Office of Audit Services
Office of Inspector General
Department of Health and Human Services

January 19, 2018

9:00 a.m.

Location: 2123 Rayburn House Office Building

Testimony of Gloria L. Jarmon
Deputy Inspector General for Audit Services
U.S. Department of Health and Human Services, Office of Inspector General

Good morning, Chairman Harper, Ranking Member DeGette, and Members of the Subcommittee. I am Gloria Jarmon, Deputy Inspector General for Audit Services for the Office of Inspector General (OIG), U.S. Department of Health and Human Services. I appreciate the opportunity to appear before you to discuss our recently published audit report on the food-recall process at the Food and Drug Administration (FDA) and our recommendations for improving that process.

Food recalls are critical to preventing people from consuming food that may be harmful. Prior OIG reviews have focused on FDA oversight of food recalls and inspections of food facilities.¹ The FDA Food Safety Modernization Act gave FDA new statutory authority, including the authority to order mandatory food recalls. Our recent audit, released at the end of December 2017, was aimed at determining whether FDA is fulfilling its responsibility to safeguard the Nation's food supply now that it has mandatory recall authority.²

This audit reviewed documentation for 30 recalls, including 23 Class I and 7 Class II recalls, which were judgmentally selected from the 1,557 food recalls reported to FDA between October 1, 2012, and May 4, 2015. In a Class I recall, there is a reasonable probability that the use of or exposure to the product could cause serious adverse health consequences or death. In a Class II recall, the use of or exposure to a product may cause temporary or medically reversible adverse health consequences or the probability of serious adverse health consequences or death is remote.

Because we selected a judgmental sample, the results are informative about deficiencies in FDA's food-recall oversight process but are not representative of the full population of FDA recalls. For the 30 food recalls we reviewed, we found that FDA's food-recall process was not always effective and efficient in ensuring the safety of the Nation's food supply. Specifically, we identified deficiencies in:

- FDA's oversight of recall initiation,
- FDA's monitoring of recalls, and
- the recall information captured and maintained in FDA's electronic Recall Enterprise System (RES).

¹ *Review of the Food and Drug Administration's Monitoring of Pet Food Recalls* (A-01-07-01503, August 2009). Available online at <https://oig.hhs.gov/oas/reports/region1/10701503.pdf>. *Review of the Food and Drug Administration's Monitoring of Imported Food Recalls* (A-01-09-01500, June 2011). Available online at <https://oig.hhs.gov/oas/reports/region10/10901500.pdf>. *Challenges Remain in FDA's Inspections of Domestic Food Facilities* (OEI-02-14-00420, September 2017). Available online at <https://oig.hhs.gov/oei/reports/oei-02-14-00420.pdf>.

² *The Food and Drug Administration's Food-Recall Process Did Not Always Ensure the Safety of the Nation's Food Supply* (A-01-16-01502, December 2017). Available online at <https://oig.hhs.gov/oas/reports/region1/11601502.pdf>.

My testimony today focuses on key aspects of these three findings and OIG's recommendations to FDA for improving its food-recall process. I will also highlight some of the actions that FDA officials told us that they took in response to the Early Alert of Significant Preliminary Findings (early alert) we issued in June 2016, in advance of the audit report. That early alert notified FDA that preliminary evidence suggested it did not have policies and procedures in place to ensure firms initiated food recalls promptly. According to FDA, our review and early alert were catalysts to major changes by FDA to strengthen its oversight of the food-recall process and its enforcement strategies. Although progress appears to have been made, more is needed to protect the Nation's food supply.

FDA's Oversight of Food Recalls

A recall is a firm's³ removal or correction of a marketed product that FDA considers to be in violation of the Federal Food, Drug and Cosmetic Act (FD&C Act) and against which FDA would initiate a legal action (e.g., seizure). When FDA learns about a potentially hazardous product, FDA may discuss the possibility of a recall with a firm without specifically requesting a recall. If the firm decides to recall the product, the firm's action is considered a voluntary recall. When a firm promptly initiates a voluntary product recall, FDA does not need to take further action to initiate the recall.

If a firm fails to voluntarily recall the product, or FDA determines that the recall is ineffective, FDA may take appropriate regulatory action. One action that FDA may consider is a mandatory recall. To use its mandatory recall authority, FDA must determine that there is a reasonable probability that the food is adulterated under section 402 of the FD&C Act or misbranded under section 403(w) of the FD&C Act and that it will cause serious adverse health consequences or death to humans or animals.⁴ FDA's mandatory recall procedures require it to complete a Health Hazard Evaluation (HHE), a tool used by FDA to evaluate the health hazard presented by a product, classify a recall, and assess a firm's recall strategy, before using its mandatory recall authority.⁵

Deficiencies in FDA's Oversight of Recall Initiation

Our review of FDA's oversight of firm-initiated recalls determined that FDA (1) could not always ensure that firms initiated recalls promptly and (2) did not always evaluate health hazards in a timely manner.

³ Firms are generally individuals or entities responsible for the product's manufacture and distribution.

⁴ Section 206 of the FSMA, P.L. No. 111-353 (enacted January 4, 2011), amending and adding section 423 to the Federal Food, Drug, and Cosmetic Act.

⁵ *Mandatory Food Recalls*, document number ORA-OEIO.055, version 1.1, dated December 27, 2012.

FDA Could Not Always Ensure That Firms Initiated Recalls Promptly

We found that FDA could not always ensure that firms initiated recalls promptly because FDA did not have adequate procedures to ensure that firms take prompt and effective action in initiating voluntary recalls.

For the 30 recalls that we reviewed, initiation of the recall occurred anywhere from 9 days before to 303 days after FDA learned that the product was potentially hazardous. Firms initiated these recalls an average of 57 days (with a median of 29 days) after FDA learned of the potential hazard. For example, one firm did not initiate a Class I recall of an adulterated dietary supplement until 303 days after receiving a warning letter from FDA stating that the product was adulterated. In that case, FDA and the firm disagreed about whether the supplement was lawful.

We found that FDA had not established risk-based internal timeframes for reaching certain milestones in the recall process, such as when FDA recall staff should request that firms voluntarily recall their products, which delayed it from taking further action in some recalls. For instance, when firms were reluctant to voluntarily initiate timely recalls, delays were more likely, and FDA's food-recall initiation process could not ensure the efficiency and effectiveness of food recalls. If FDA had established risk-based internal timeframes, it might have identified reluctant firms earlier in the food-recall process and taken appropriate action to protect public health.

FDA Did Not Always Evaluate Health Hazards in a Timely Manner

FDA uses an HHE to evaluate the health hazard presented by a product, classify a recall, and assess a firm's recall strategy. If a product is identical or similar to a previously classified recalled product, a precedent HHE may be used. FDA was unable to rely on a precedent HHE for 14 of the 30 recalls that we audited. In those 14 recalls, completion of the HHE ranged from 8 working days before FDA learned of a planned or in-progress recall to 209 working days after learning of a planned or in-progress recall. On average, FDA took 47 working days (with a median of 27 working days) to complete the HHEs associated with these 14 recalls.

We found that FDA did not complete some HHEs in a timely manner for several reasons. One reason was that FDA district staff located throughout the country did not always submit a recall alert about a planned or in-progress food recall to the RES within the timeframe outlined in its procedures. These recall alerts trigger the initiation of the HHE process. According to FDA's Regulatory Procedures Manual (RPM), a recall alert should be submitted as soon as possible, but preferably within 24 hours of the district learning of a planned or in-progress recall. For the 30 recalls that we audited, FDA district staff submitted the recall alert an average of 34 days after learning of a planned or in-progress recall.

Without a timely HHE, FDA could not send out to firms timely notification letters with FDA's formal written assessment of the firms' recall strategy and any suggested strategy revisions or request periodic status reports. Furthermore, without a timely HHE, FDA could not establish whether there was a reasonable probability that the product would cause serious adverse health consequences or death. Because FDA must establish this reasonable probability in order to

exercise its mandatory recall authority, FDA was not always in a position to determine whether it should order a mandatory food recall.

Key OIG Recommendations for Improving FDA's Oversight of Recall Initiation

To improve FDA's oversight of recall initiation, we recommended that FDA establish set timeframes for:

- discussing the possibility of a voluntary recall with a firm and
- initiating the use of its mandatory recall authority after it has made the determination that the legal standard for use of that authority has been met and a firm is not willing to voluntarily conduct a recall.

In addition, we recommended that FDA take several specific actions aimed at ensuring that HHEs are completed in a timely manner.

Deficiencies in FDA's Monitoring of Recalls

We identified several deficiencies in FDA's monitoring of firm-initiated recalls. Specifically, we found that FDA did not always (1) issue audit check assignments at the appropriate level, (2) complete audit checks in accordance with its procedures, and (3) collect timely and complete status reports from recalling firms.

FDA Did Not Always Issue Audit Check Assignments Consistent With the Level in the Proposed Audit Program

FDA monitoring district staff should establish a proposed audit program for monitoring a recall, which should include a timetable for reviewing the recall status and the level and type of audit checks. A recall "audit check" is a visit, telephone call, or letter (or a combination thereof) from an FDA district office to a consignee (anyone who received, purchased, or used the product being recalled) of a recalled product intended to verify that the consignee has been notified of the recall and has taken appropriate action. Depending on the audit check level, district offices should contact a certain percentage of consignees. FDA relies on the recalling firm to provide it with a distribution list of consignees that received the recalled product.

For 8 of the 27 recalls in our audit that required audit checks, FDA assigned fewer audit checks to its district offices than were called for by the audit check level in the proposed audit program. For example, in one Class I recall, the audit program proposed audit check Level A, which required the district offices to contact all 19 of the domestic consignees that received the recalled product, but FDA assigned audit checks for only 12 consignees.

FDA did not always assign audit checks consistent with the audit check levels in the audit plan because oversight of FDA's recall coordinators was insufficient, and the consignee distribution lists that FDA obtained from recalling firms were not always complete or accurate. Because

fewer audit checks were assigned than were required by the audit check level, there was an increased risk that consignees were not aware of the recall and recall instructions.

FDA Did Not Always Complete Audit Checks in Accordance With Its Procedures

We found that FDA did not always complete audit checks in accordance with timeframes set out in its procedures. As a result, FDA could not ensure that consignees took timely, appropriate action to remove harmful products from retail stores and from other points in the distribution chain. FDA's RPM states that FDA should normally assign audit checks to its district offices within 10 days of the firms' recall communication with consignees. The RPM states that the district office should consider the audit check assignments "high priority" and complete them within 10 days of assignment, if possible. In certain cases, FDA can use State agencies and third-party contractors to conduct audit checks.

For 5 of the 30 recalls in our audit, FDA determined that audit checks were not required. For 21 of the remaining 25 recalls that required audit checks, FDA did not complete the audit checks within the timeframes set out in its procedures. On average, the audit checks for these 21 recalls took 118 days (with a median of 69 days) to complete from the time of the firms' first recall communication. In one case, FDA did not complete the final audit check related to a Class I recall of a mislabeled product until 547 days after the firm first notified its consignees of the recall. Three of the 18 audit checks that FDA conducted for this recall were conducted more than 300 days after the firm issued the recall communication. This means that the mislabeled product was still on the shelves of three retail stores, and consumers remained at risk.

For all 21 recalls that did not have audit checks completed in a timely manner, we noted that FDA did not obtain assistance from State agencies or third-party contractors to help complete the audit checks. We also found that communication among the FDA staff conducting audit checks, recall coordinators, and district offices was not always effective in ensuring that audit checks were completed in a timely manner. In addition, none of FDA's data systems could be used to assist staff with tracking the status of audit checks. As a result, FDA could not ensure that consignees took timely, appropriate action and removed harmful products from the market.

FDA Did Not Always Collect Timely and Complete Status Reports From Recalling Firms

FDA should request periodic status reports from recalling firms so that FDA can monitor and assess the progress of a recall. Status reports should contain specific information, including the number and results of the firm's effectiveness checks. Effectiveness checks help firms and FDA verify that all known, affected consignees have received notification about a recall and have taken appropriate action.

FDA did not always collect timely status reports. For 11 of the 30 recalls covered by our audit, FDA either did not request or did not collect status reports. For the remaining 19 recalls, the average number of days for FDA to collect the first status report was 143 days (with a median of 122 days and range of 14 to 605 days) after the recall was initiated. In addition, when FDA collected status reports, they were not always complete. Of the 19 recalls in which FDA

obtained at least 1 status report, we found that status reports associated with 5 recalls did not contain complete effectiveness check information.

In one Class I recall that we audited, FDA did not officially request status reports from the recalling firm until 57 days after the recall was initiated and did not receive a status report until 605 days after the recall was initiated. There was not any evidence that FDA followed up with the firm about the status report in that timeframe, and, in addition to being untimely, the status report that FDA received did not contain information about the number and results of the firm's effectiveness checks.

FDA's procedures to collect timely and complete status reports from recalling firms were inadequate because they did not require staff to request status reports at the time a recall was initiated. In addition, FDA did not always follow up with firms when status reports were not provided, were provided late, or were incomplete. Without obtaining timely and complete status reports from a recalling firm, FDA could not adequately monitor the progress and effectiveness of the recall and assess whether additional action was necessary to protect the public.

Key OIG Recommendations for Improving FDA's Monitoring of Recalls

To improve FDA's monitoring of recalls, we recommended that FDA:

- take steps to ensure that audit checks are assigned at the level specified in the audit program and to ensure the completeness and accuracy of consignee distribution lists,
- take specific actions to help ensure that audit checks are completed in a timely manner,⁶ and
- implement procedures for requesting status reports at the initiation of a recall and follow up with firms that do not provide timely or complete status reports.

Deficiencies in FDA's Electronic Recall Enterprise System

Our review of FDA's electronic recall data system determined that FDA did not always (1) track key recall data and (2) maintain accurate recall data.

FDA Did Not Always Track Key Recall Data in RES

FDA uses RES, an electronic data system, to help manage recalls. RES also provides a central, searchable database that FDA can use to track information, generate reports about recall activities, and disseminate those reports.

We found that RES did not have a field for tracking all information necessary for FDA to effectively monitor recall activities and assess the timeliness of recalls. Specifically, RES did

⁶ Specifically, we recommended that FDA increase its use of third parties to perform audit checks, strengthen internal communication during the audit check process, and improve the ability of FDA information systems to track and monitor the status of audit checks.

not track the date that FDA learned a product was potentially hazardous. Therefore, FDA could not use RES to measure the amount of time between the date FDA learned that a product was potentially hazardous and the date a firm initiated a voluntary recall.

For example, in a Class I recall involving hazelnuts contaminated with *Salmonella*, FDA learned that the hazelnuts were potentially hazardous on December 2, 2012. The firm initiated the recall on May 2, 2013. However, because the RES did not have a field for the date that FDA first learned the product was potentially hazardous, FDA could not use the RES to calculate that it took the firm 151 days to initiate the recall after FDA first learned the product was potentially hazardous.

FDA staff documented the date that FDA learned a product was potentially hazardous only in the recall files. FDA officials stated that tracking this date for all recalls would be time consuming and difficult because the date may be located in different FDA systems or obtained from sources outside of FDA. However, without tracking this date in the RES, FDA could not effectively identify and respond to firms that were not prompt in recalling food products that FDA was aware presented a risk to public health.

FDA Did Not Always Maintain Accurate Recall Data

FDA did not always enter accurate recall initiation dates in the RES. The RES User Manual defines the recall initiation date as the “date that the recall action was initiated by a company.” However, for 11 of the 30 recalls we sampled, we determined that the recall initiation date in RES was off by an average of 16 days (with a median of 4 days). The inaccurate recall initiation dates ranged from 1 day before the initiation date inputted into the RES to 89 days after.

For example, in a Class I recall involving undeclared allergens in a dietary supplement, June 5, 2013, was entered as the recall initiation date. Based on a review of the recall file, however, we determined that recall was not initiated until the firm began notifying its consignees of the recall on September 2, 2013. The initiation date in the RES was incorrect by approximately 3 months (89 days).

FDA’s RES User Manual did not clearly define the term “recall initiation date” and, therefore, FDA staff input other dates into the RES. In the Class I recall discussed above, the recall coordinator explained that she entered the date the firm started discussing a possible recall as the recall initiation date. In addition, FDA did not have a data quality assurance process to help ensure that RES data were both accurate and complete.

Without an accurate recall initiation date documented in the RES, FDA could not use the RES to determine the length of time it took a firm to initiate a recall. As a result, FDA did not have assurance that the data in the RES were accurate and that the RES was reporting correct information.

Key OIG Recommendations for Improving the Completeness and Accuracy of FDA's Electronic Data Systems

To help ensure the completeness and accuracy of data in its data systems and give FDA staff involved in managing recalls access to information about key events, we recommended that FDA:

- consider adding to RES or another FDA system a field for the date FDA learns of a potentially hazardous product,
- establish performance measures for the amount of time between the date FDA learns of a potentially hazardous product and the date a firm initiates a voluntary recall,
- clarify the definition of “recall initiation date” in its policies and procedures and ensure a consistent understanding of “recall initiation date” among recall personnel, and
- develop and implement a data quality assurance process to ensure that the RES contains accurate information.

FDA Initiatives to Improve the Food-Recall Process

In response to our early alert, FDA informed us of several changes it had taken to improve the way it manages and oversees food recalls.

In April 2016, FDA established a team of senior FDA leaders charged with making decisions during the most challenging and high-risk food-recall cases. This team is called SCORE, which stands for Strategic Coordinated Oversight of Recall Execution. According to FDA, SCORE has reviewed and directed a large number of operations in the most difficult cases that FDA has faced since we issued our early alert, and has made a difference in ensuring that FDA acts quickly to investigate and reduce consumer exposure to potentially harmful foods on the market.

In September 2016, FDA's Office of Regulatory Affairs (ORA) designed and implemented a plan to audit ORA's recall program across all regulated product areas. ORA described the program as a “quality system recall audit plan” that provides for both “traditional auditing and continuous monitoring of the recall program.”

Finally, in December 2016, ORA completed a project charter that implemented a recall strategic plan. According to FDA, this plan is designed to identify strategic priorities that optimize FDA's policies and procedures regarding the recall of FDA-regulated products that pose a public health risk.

While we have not had the opportunity to assess the impact of these changes, we are encouraged by the proactive steps that FDA has taken to improve the food-recall process.

Conclusion

In its comments on our report, FDA agreed with our conclusion that it needs to help ensure that recalls are initiated promptly in all circumstances and said that it will consider the results of our review as it continues to operate the SCORE initiative. Among other things, FDA stated that it is initiating a new quality system audit process and a plan to provide early notice to the public and more guidance to staff. We appreciate the steps FDA has taken as well as the steps it plans to take to address the vulnerabilities we identified during our audit.

We also appreciate the Subcommittee's interest in our audit and thank you for the opportunity to testify on ways for FDA to improve its oversight of the food-recall process. Conducting audits, evaluations, and inspections aimed at food safety is a priority for OIG and remains key to our mission of protecting the health and safety of the American people. Since FY 2015, OIG has increased its efforts to oversee FDA by (1) assessing FDA's implementation of new authorities, (2) monitoring existing FDA programs, (3) reviewing FDA's readiness to address new threats to public health and safety, and (4) investigating FDA's administration and fraud, waste, and abuse. OIG will continue to work with FDA and Congress to help ensure the safety of the Nation's food supply.

I look forward to answering your questions.

Mr. HARPER. Thank you, Ms. Jarmon. The Chair will now recognize Mr. Stearn for 5 minutes for the purposes of a summary of his written testimony. Thank you and welcome.

STATEMENT OF DOUGLAS W. STEARN

Mr. STEARN. Thank you, sir. Good morning, Chairman Harper, Ranking Member DeGette, and members of the subcommittee. I am Douglas Stearn, Director of Enforcement and Import Operations in the Office of Regulatory Affairs and the Acting Deputy Director for Regulatory Affairs for the Center for Food Safety and Applied Nutrition.

We appreciate the opportunity to provide you with information about how we oversee recalls of FDA-regulated products. FDA is committed to continuously improving our practices to ensure that food recalls are initiated, overseen, and completed promptly and effectively to best protect consumers.

In this regard, we appreciate the Office of Inspector General's focus on this subject. I would like to thank the committee for the opportunity to report on major changes FDA has made in response to OIG's investigation. When we learn about a food in the marketplace that may be unsafe, we must act quickly to keep people from getting sick or being harmed.

FDA has authority to act in a variety of ways, but often the fastest and most efficient way to ensure unsafe foods are recalled quickly is to work directly with the involved companies while simultaneously providing the public with timely, accurate information that they can act on, making sure FDA has effective recall practices in place, and we take immediate action to address unsafe foods are high priorities for the agency.

FDA has wide-ranging oversight responsibilities. In the foods areas, FDA is responsible for oversight and regulation of more than 300,000 registered food facilities and more than 12 million lines of imported food products per year. FDA is also responsible for overseeing industry recalls of food products. In the most recent fiscal year, FDA oversaw more than 3,600 food product recalls.

The recent OIG review of a selected group of 30 food recalls initiated between 2012 and 2015 found some unacceptable delays in the removal of food from the market. This group included a number of challenges, including criminal behavior from a firm that hid critical information; new technology used to link clinical samples to their source; and key questions about how broad a recall should be.

One of the most significant steps FDA has taken was in April 2016. FDA established a team of senior leaders charged with reviewing complex or unusual food safety situations and determining the proper action to address the problem. SCORE, the Strategic Coordinated Oversight of Recall Execution, meets at least weekly and makes decisions about what actions to take.

SCORE has made a difference in addressing complicated, challenging, and unusual incidents. The team has been involved in cases that range from lead contamination of a dietary supplement, Salmonella contamination of powdered milk, E. coli O157:H7 in soy nut butter, to Listeria in hummus, soft cheese, and smoked fish.

In addition to facilitating recalls and import alerts for the detention of products entering the U.S., SCORE helped expedite the reg-

istration suspension of two food facilities, actions that prohibit food distribution after recall. In addition to SCORE, FDA has put in place several additional procedural changes. Last year, after a comprehensive review of our recall process, we developed a new strategic plan to improve recall management. The plan helps to standardize how FDA assesses a company's recall efforts, establishes monitoring of recall activities, provides additional training and guidance to our staff to monitor and assess recall effectiveness, and increases the timeliness and amount of recall information provided to the public.

The procedural changes FDA has completed since the OIG investigation establish a monthly monitoring system and regular audits, improve recall recommendations and recall audit check assignments, expand third-party recall audit checks, improve the pathway for foreign suppliers to provide information about recalls to FDA, and create a set of best practices for our State partners.

FDA will continue to implement additional changes that will continue to improve how we protect the public through the recall process and through consumer messages. FDA has improved its recall classification process and now averages 13 to 15 days, down dramatically from a year earlier.

Furthermore, the agency is focused on providing more information to consumers in a number of ways. We now publicize recalls prior to classification. Yesterday, we released a draft guidance to improve public awareness in additional recall areas. And the Commissioner also announced a way to share additional information with consumers during recalls, such as specific stores where recalled food may have been sold.

FDA is also currently pursuing major initiatives that have implications for the oversight of recalls in the future. The Food Safety Modernization Act shifts the focus of the food safety system from responding to contamination to preventing it and will change how companies prevent and respond to food safety issues.

In addition, FDA field operations have recently undergone a reorganization to meet today's challenges by specializing recall coordinators and other FDA staff.

Thank you for the opportunity to discuss FDA's recall processes. I would be happy to answer any questions you may have.

[The prepared statement of Mr. Stearn follows:]

STATEMENT OF
DOUGLAS W. STEARN, J.D.
ACTING DEPUTY DIRECTOR FOR REGULATORY AFFAIRS
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION AND
DIRECTOR OF THE OFFICE OF ENFORCEMENT AND IMPORT OPERATIONS
OFFICE OF REGULATORY AFFAIRS
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS
COMMITTEE ON ENERGY AND COMMERCE
U.S. HOUSE OF REPRESENTATIVES

“SAFETY OF THE U.S. FOOD SUPPLY: CONTINUING CONCERNS OVER THE
FOOD AND DRUG ADMINISTRATION'S FOOD RECALL PROCESS”

JANUARY 19, 2018

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good morning, Chairman Harper, Ranking Member DeGette, and members of the Subcommittee. I am Douglas Stearn, director of the Office of Enforcement and Import Operations in the Office of Regulatory Affairs of the U.S. Food and Drug Administration (FDA or the Agency) within the Department of Health and Human Services. Currently, I am serving as the acting deputy director for regulatory affairs at the Center for Food Safety and Applied Nutrition within FDA. I am also the co-chair of the Strategic Coordinated Oversight of Recall Execution (SCORE).

We appreciate the opportunity to provide you with information about how we oversee recalls of FDA-regulated products that can harm consumers. FDA is committed to continuously improving our policies and practices to ensure that food recalls are initiated, overseen, and completed promptly and effectively to best protect consumers. In this regard, we appreciate the Office of Inspector General's (OIG's) focus on this subject and would like to thank the committee for the opportunity to report on major changes FDA has made in response to OIG's investigation.

When we learn about a food in the marketplace that may be unsafe, we must act quickly to keep people from getting sick or being harmed. If foodborne illness has already occurred, we also must act quickly to keep more people from becoming ill. FDA has authority to act in a variety of ways, but often the fastest and most efficient way to ensure unsafe foods are recalled quickly is by working directly with the involved companies while simultaneously providing the public with timely, accurate information that they can act on. Making sure FDA has effective recall practices in place, and that we take immediate action to address unsafe foods, are high priorities of the Agency. Our recall authorities – and how we deploy them – are a cornerstone of our vital consumer protection mission.

ROLES OF INDUSTRY AND FDA IN CONDUCTING RECALLS

FDA has wide-ranging oversight responsibilities. In the foods area, FDA is responsible for inspecting more than 88,000 domestic registered food facilities that manufacture, process, pack, or hold food. In addition to domestic food facilities, FDA is also responsible for ensuring the safety of food imported from the more than 212,000 registered foreign food facilities, producing more than 12 million food commodity import occurrences into the United States in fiscal year 2016. In addition to inspections of those food facilities, FDA is responsible for overseeing the industry's recall of food products that present a risk of injury or gross deception or are otherwise violative. In recent years, FDA has overseen thousands of food recalls annually. In FY 2017 alone, FDA oversaw more than 3,600 product recalls.

Until the FDA Food Safety Modernization Act (FSMA) was signed into law in 2011, with the exception of infant formula, food recalls were defined as voluntary actions that were dependent on manufacturers and distributors to effectively discharge their recall responsibilities. Recalls were considered exclusively as voluntary alternatives to court actions against non-compliant firms that FDA might otherwise initiate. FDA's role in this voluntary process was to monitor recalls and assess the adequacy of firms' efforts so that the Agency could take additional action when necessary. Subpart C of Part 7 of FDA's regulations (Title 21, *Code of Federal Regulations*, Sections 7.40-59) governs the voluntary product recalls, and FDA also has published guidance for recalling firms (*see <https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>*). FDA's guidance on voluntary recalls describes actions that FDA and the industry can take to carry out their respective recall responsibilities. The underlying premise of this guidance is that firms producing and marketing FDA-regulated products assume a responsibility to timely remove violative products from the marketplace when removal is necessary to protect the public health.

Under FSMA, FDA has authority to mandate a recall of a food product when FDA determines that there is a reasonable probability that an article of food is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act) and/or is misbranded under section 403(w) of the FD&C Act and where there is a reasonable probability that the use of or exposure to such food would cause serious adverse health consequences or death to humans or animals. In May 2015, FDA issued guidance explaining the mandatory recall provision. (*See <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm445428.htm>*.) We believe FDA's mandatory recall authority has played an important role in motivating firms to initiate voluntary recalls. When the firm does not take the appropriate actions, FDA can initiate use of the mandatory recall authority, which it has done on two occasions.

The cooperation and transparency of industry are critical in ensuring that violative products are promptly and effectively removed from the marketplace. FDA urges recalling firms to notify the Agency as soon as they determine a recall is appropriate. In addition, registered food facilities are required to report to FDA through the Reportable Food Registry when there is a reasonable probability that the use of, or exposure to, an article of food (applies to all FDA-regulated categories of food and feed, except dietary supplements and infant formula) will cause serious adverse health consequences or death to humans or animals. In many other cases, inspectional findings, sampling results, or other information in the Agency's possession leads to discussions with firms that can result in a firm's decision to recall a product. FDA typically asks firms to provide information to the Agency about the recall, including the reason for the recall, how the problem occurred, the extent of the problem, how and when the firm discovered the problem, where the product was distributed, and any consumer or supplier complaints.

Recalling firms and FDA generally work collaboratively to develop a recall strategy or to review the firm's existing recall strategy. The recall strategy allows FDA to determine the steps it must take to address the specific circumstances, which may include making certain that all products that need to be recalled are, in fact, recalled; helping to locate the product subject to the recall; assisting to identify the cause of the problem; and checking associated firms or products to determine if the problem could be more widespread. FDA uses information it learns during recalls to help prevent future problems and to identify similar problems if they arise in the future.

Throughout the course of the recall, it is the firm's responsibility to determine whether the recall is progressing satisfactorily by performing effectiveness checks. These checks help to verify that all known, affected consignees have received notification about a recall and have taken appropriate action. At the same time, FDA conducts "audit checks" to assess the effectiveness of a firm's recall efforts.

Even though the firm recalling the product may publicize its recall, FDA will further publicize a recall when it believes the public needs to be alerted about a serious hazard. Notifying the news media is an effective way to inform large numbers of people that a widely distributed product has been recalled. FDA also provides notifications about all recalls of FDA-regulated products in its weekly FDA Enforcement Report. (See <https://www.accessdata.fda.gov/scripts/ires/index.cfm>.)

FDA WORK WITH FIRMS DURING RECALLS

FDA is committed to working with recalling firms whenever possible to facilitate the orderly and prompt removal of a violative product from the marketplace, and has a variety of mechanisms in place to achieve this goal. FDA has field recall coordinators located throughout the country to act as the point of contact for a recalling firm and to assist firms with a recall. The recall coordinators provide a recalling firm with information about the recall process and are available to work closely with the firm throughout the course of the recall. For example, recall coordinators assist the firm in determining an appropriate recall strategy, review the recalling firm's notification letter to customers affected by the recall, and coordinate the appropriate destruction, reconditioning, or disposition of the recalled product.

In addition, FDA has developed "model" press releases available for use by recalling firms that need to issue press releases to inform the public about a recall. These model press releases help ensure that all appropriate information about the recalled product is accurately and appropriately conveyed to the public. Further, FDA encourages recalling firms to consult with their local recall coordinators before issuing press releases.

To assist firms in communicating their recall actions, and to help ensure that the public is informed, FDA posts firms' press releases on the Agency's website. FDA will also post photos of the recalled food product if provided by the firm. The use of product photographs for food recalls has also proven successful and useful to consumers.

FDA'S COMMITMENT TO IMPROVING RECALL PROCESSES, DISCLOSURE, AND EXECUTION

The recent OIG review of a judgmental sample of thirty food recalls initiated between 2012 and 2015 found some unacceptable delays in the removal of food from the market. As noted in the report, these were among the most complex recalls FDA deals with, and these recalls presented unique challenges, including: criminal behavior from a firm that hid critical information from the Agency; using new technology that links information from outbreaks to facilities; and putting information together from disparate sources to determine the appropriate expansion of a recall once an initial lot of contaminated food has been recalled. These are the types of challenges we are committed to addressing. Since the time period examined in this report, we have taken – and continue to take – OIG's recommendations seriously, and FDA leadership worked quickly to put in place measures to address the proposals that OIG outlined.

One of the most significant steps FDA has taken was in April 2016, by establishing a team of senior leaders charged with reviewing complex or unusual food safety situations and determining the proper action to address the problem if it is not clear. The team meets at least weekly and makes recommendations about what actions to take and how to make sure they occur.

This team of senior leaders, called SCORE, which stands for "Strategic Coordinated Oversight of Recall Execution," has made a remarkable difference in addressing more complicated, challenging, or unusual incidents. SCORE has been involved in various disparate cases including lead contamination of a dietary supplement, *Salmonella* contamination of powdered milk, *E. coli* O157:H7 in soy nut butter, and *Listeria* in hummus, soft cheese, and smoked fish. In addition to facilitating recalls and import alerts for the detention of products entering the United States, SCORE initiated or helped to expedite the process for suspending the registration of two food facilities, actions that block the facilities' ability to distribute food to the marketplace.

In addition to the establishment of SCORE, FDA has put in place several additional procedural and policy changes. Last year, after a comprehensive review of our recall process, we developed a new strategic plan that outlines actions to improve FDA's recall management. The plan helps to standardize how FDA assesses a company's recall efforts, establishes monitoring of the

Agency's recall activities, provides additional training and guidance to our staff involved in recall efforts so they can properly monitor and assess the effectiveness of a recall, and increases the timeliness and amount of recall information provided to the public.

The changes FDA has completed regarding its internal procedures since the OIG investigation include the following:

- Established a monthly monitoring system that indicates to field personnel when a recall activity appears to be slower.
- Completed a baseline audit of recalls in each district indicating the timeliness of each step throughout the recall process that provides a basis for field management to address untimely performance or challenges.
- Revised procedures to clarify when FDA may informally recommend that a firm cease distribution of, or recall a violative product to improve efficiency in processing cases. (See Regulatory Procedures Manual (RPM) 7-5-1.)
- Updated FDA's Recall Audit Check Report and its instructions to ensure better documentation of recall audit checks, which is necessary to document the receipt of recalled product and notification of the recall, as well as the appropriate disposal of the product as instructed in the recall notification. (See IOM Exhibit 7-3.)
- Expanded our third-party recall audit check contract to increase the number of recall audit checks performed.
- Added fields in the Recall Enterprise System, FDA's internal recall database, to allow for more complete evaluation of recall time lines, including the Recall Determination Date, the Recall Audit Check Assignment Date, and the Recall Audit Check Completion Date to provide a greater ability to monitor open recalls to ensure that the recall is completed and terminated more promptly.
- Created a central location and enhanced communications to foreign firms and governments to ensure that FDA initiates the oversight of recalls originally initiated by foreign suppliers.
- Created a set of best practice recommendations for States to facilitate communication and coordination of recall activities in response to a Class I recall or a recall related to an outbreak.

In addition to the list above, the Agency anticipates implementing additional revisions, procedural enhancements, and new policies that will continue to improve how we protect the public through the recall process and in our communications to consumers.

FDA has also improved its recall classification process, speeding it up by enhancing our tracking of individual cases throughout the classification process, cross-training employees, and utilizing cross-trained employees during surge periods. As a result of a change that began in fiscal year 2017, FDA now averages 13-15 days to classify food and cosmetic recalls from the recall recommendation, down from 79 days only a year earlier. FDA intends to continue efforts to further shorten this time period.

IMPLICATIONS FOR FOOD RECALL PROCESSES FROM OTHER FDA CHANGE INITIATIVES

FDA is also currently pursuing major initiatives that have implications for how the Agency oversees its recall functions into the future. Over the last several years, the Agency has been focused on finalizing and implementing FSMA, the most sweeping reform of food safety laws in almost 70 years, which shifts the focus of the U.S. food safety system from responding to contamination to preventing it. One of the preventative measures FSMA addresses concerns how firms conduct recalls. As part of the FSMA regulation on preventive controls for human food, where a hazard analysis identifies a need for a preventive control, the facility must have a written recall plan that includes procedures to notify consignees, to notify the public when necessary, to conduct effectiveness checks, and to appropriately dispose of recalled product. In addition, FDA field operations in the Office of Regulatory Affairs have recently undergone a reorganization to meet the challenges of keeping pace with the scientific innovation, globalization, and increasing breadth and complexity of regulated products, as well as new legal authorities. With ORA's program alignment, FDA field staff now specialize in specific FDA-regulated product areas. Among the FDA field staff who have become specialized are the recall coordinators responsible for working with firms on food recalls, as noted above. These field staff are developing deeper knowledge of FDA's food safety standards, food inspections, and regulatory tools applicable to food, and a closer relationship with the Center for Food Safety and Applied Nutrition.

CONCLUSION

Thank you for the opportunity to discuss FDA's recall process. I would be happy to answer any questions you may have.

Mr. HARPER. Thank you very much, Mr. Stearn, for your summary of your testimony. At this time, the Members will each have 5 minutes to ask questions of you, and I'll recognize myself for that purpose. And I'll start with you, if I may, Mr. Stearn, to ask you some questions.

The Office of Inspector General and the Government Accountability Office, in previous audit reports dating back to 2009, has raised concerns about the FDA's monitoring of food recalls, such as verifying to make sure that retail grocery stores know about the recalls and the products have been removed from their shelves. Yet the December 2017 report from OIG finds that monitoring recalls is still a problem for FDA.

Why is this still a problem? And why should the subcommittee believe that the FDA is going to get it right this time?

Mr. STEARN. Thank you for your question, sir. I answer it a number of ways. First, I would say, we do take this issue seriously. I've outlined in my testimony today, and in greater form in my written testimony, a number of actions that we have already taken, and those included those that I just outlined in terms of establishing a group of senior leaders and audit process and additional procedures.

I would say, too, that the oversight of the food safety system is a large-scale enterprise, and we are actively working on FSMA implementation, which is the overall solution that we think will bend this curve in terms of food safety, and it is something that we have been in great dialogue with with all of the other places in the food safety system.

Mr. HARPER. I think it would be safe to say that a goal of FDA, through its implementation of FSMA, is to reduce the incidents of foodborne illness in the United States. Is that fair to say?

Mr. STEARN. Yes, sir.

Mr. HARPER. Is that FDA goal documented somewhere, and is there a timeframe?

Mr. STEARN. Well, I think, in terms of the HHS initiatives and agency initiatives, there is language that speaks to that. I can say, as somebody who is involved in FSMA implementation myself—I am on the steering committee—it is something that we are driven to do, we have timeframes. At the same time, we think it's really important to get things right. We don't want to have to reverse back if we get a standard that's not correct. And we are actively out implementing a lot of the provisions of FSMA, inspections have started in a number of areas, the rules have been written, and so forth. So we have a lot of actions that have been taken place.

Mr. HARPER. Does the FDA view improvements to its food-recall process as part of achieving this public health goal?

Mr. STEARN. We do.

Mr. HARPER. And are you satisfied that you're putting the metrics in place where we can actually do a quantitative view of what your improvement and process is going to be?

Mr. STEARN. Yes, sir. We've taken a number of things to create more metrics and standards. We have an audit process in the steps that I've outlined which tracks during recalls the steps in between each of the, sort of, critical control points, each of the steps that take place, and we do think that that's important. There's always

more we can do, and some of these issues can be complicated, but we do think that that's important.

Mr. HARPER. I know that the public expects, you know, not to maybe do it that day, but the timeframe, that you've got to shrink that. Do you believe that you're in the process to do that? To reduce greatly the number of days that it takes to complete this process when there is a recall?

Mr. STEARN. We do.

Mr. HARPER. OK. Ms. Jarmon, if I can ask you a few questions. What deficiency identified in the report does the HHS OIG view is the most serious, and why?

Ms. JARMON. As you know, there were several deficiencies identified, but we feel like it's so important that there's better control over the oversight of firm's initiation of food recalls, and that the health hazard evaluations are done sooner. We have several examples in our report where Health Hazard Evaluations weren't done until, you know, in some cases over 100 days. I think, on average, 57 days. And it's so important that that's done so that there's better information that FDA would have about what the harm is of the products. We think that's the most important.

Mr. HARPER. The OIG report stated that this review was conducted to determine whether FDA is fulfilling its responsibility and safeguarding the Nation's food supply now, now that it has the authority to conduct mandatory recalls.

Does the OIG see any evidence that the mandatory recall authority has been helpful to FDA's ability to carry out its mission to protect the U.S. food supply?

Ms. JARMON. We are encouraged by the progress that FDA has made. We see that there has been progress, but definitely more needs to be done, and maybe more time because a lot of the things, like Mr. Stearn mentioned, have been recently done and we haven't had an opportunity to go back and assess the progress. But the fact that the team was set up of senior executives, the SCORE team, is a positive step. The fact that there is a strategic plan now for recalls is positive. And the fact that they have the audit plan, as Mr. Stearn mentioned, is also positive, and that yesterday they issued draft guidance for improving the recall process. And all of those things could possibly be related to this legislation, so we see it as steps in the right direction.

Mr. HARPER. That's right. Thank you very much for your testimony there. The Chair will now recognize Ranking Member DeGette for 5 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman. Ms. Jarmon, I'm encouraged to hear you say that—and Mr. Stearn, I also believe it's true that the FDA is making efforts to improve their systems. The OIG's recommendations largely relate to the FDA improving its policies, procedures, and guidance. Do you agree with that?

Ms. JARMON. Yes. Many of them do relate to improving their policies and procedures and guidance, and initiating the processes sooner. We mentioned long delays.

Ms. DEGETTE. OK. So I'm wondering, what more actionable steps do you think FDA should take to improve its recalls in addition to just improving the policies and procedures? You mentioned initiating the guidance sooner. Can you expand on that?

Ms. JARMON. Yes. I mentioned doing the Health Hazard Evaluations sooner, because in our report, one of the examples that the chairman mentioned earlier about the issue that we mentioned in our Early Alert from June 2016, one related to a cheese product and one related to nut butter for the period of time from the time that FDA became aware of the hazardous product in a time that the firm initiated the recall, and that's just the initiation, more has to happen after that to get the products off the shelf.

Ms. DEGETTE. Right.

Ms. JARMON. For the nut butter, that was 165 days. For the cheese, it was 81 days. In that period of time, while we aren't specifically saying in our recommendations what the period of time should be, we believe it's reasonable to expect less time than that.

Ms. DEGETTE. The reason is, because if the food is contaminated, more people could be consuming it during that time. That is what Chairman Walden was talking about.

Ms. JARMON. Yes. And more illnesses and possible deaths.

Ms. DEGETTE. Yes. Mr. Stearn, what's the agency's response to this?

Mr. STEARN. Well, I would say a couple of things. First, as I've outlined, we've changed a number of our procedures and policies. I will say, one of the issues underneath here is to make sure that a problem is understood and that a recall actually is solving the problem.

The cheese recall that was mentioned, there were actually four different recall actions that took place during the course of that. So, you know, part of the question that gets to, you know, what action is taken, is that sufficient? One of the reasons that we put SCORE in place—and we feel that that's really critical, and also, the specialization of the field staff, which has been going on for years—is that it's important for people to have the technical expertise to make those judgments, and sometimes to order additional investigation because—

Ms. DEGETTE. Are you having difficulty getting people with the appropriate expertise?

Mr. STEARN. Well, we've got to make sure that they're at the table, and it gets more complicated. I mean, one of the things that happened during this period of time—in the nut butter recall, we started, for the first time, doing an entirely new technology, which is whole genome sequencing. We need people to understand that.

We need people to understand, you know, the rules that have been mentioned in FSMA. And so the level of specialization and the level of understanding of the supply chain needs to be high.

Ms. DEGETTE. I get it.

Mr. STEARN. Yes.

Ms. DEGETTE. Are you having difficulty attracting those people?

Mr. STEARN. Well—

Ms. DEGETTE. Yes or no will work.

Mr. STEARN. We have a number of great people in the agency, we're always looking for more.

Ms. DEGETTE. Would having a stable budget help in that situation?

Mr. STEARN. A stable budget is helpful.

Ms. DEGETTE. OK. So one issue that, as I recall—we really talked a lot about before we passed the Act—was this issue of mandatory versus voluntary recall. And I’m wondering if you’re finding, because the agency has the ability to implement mandatory recall, if that’s helping expedite the voluntary recall process more?

Mr. STEARN. We believe it is helpful for certain categories because there’s a certain point where we reach with a firm in our discussions, and the firm knowing that that power is there, does affect the result.

Ms. DEGETTE. And have you noticed, since the Act passed, the number of mandatory recalls have gone up?

Mr. STEARN. Well, what often happens, more often than not, it reaches this certain point and there is a voluntary recall. And, you know, a lot of the—so we do think that it has an impact by being there, and it’s usually in firms taking a voluntary recall, either because there’s a mandatory authority or because they know that there might be a communication from the agency. You know, those two things are actually drivers in the self-interest.

Ms. DEGETTE. Nudging them along.

Mr. STEARN. Yes.

Ms. DEGETTE. So, you know, I really appreciate the OIG’s recommendations, and I appreciate the agency’s implementing them. If you think that there’s more authority this committee needs to give to the agency to bolster that, and if you think there’s more resources or stability of resources to do this hiring, let us know, because we—this is one of these bipartisan issues. We care deeply about the safety of our constituents. Thank you. I yield back.

Mr. STEARN. Thank you.

Mr. HARPER. The gentlelady yields back. The Chair will now recognize the vice chairman of the subcommittee, Mr. Griffith, for 5 minutes.

Mr. GRIFFITH. Thank you very much, Mr. Chairman. Mr. Stearn, I know you’re here doing the best you can and that you’re trying to make everything better, but there’s some real serious questions that I have related to a number of different things, but I’m going to start with the nut butter situation, because we just touched on a couple of those.

One, you were talking about having the mandatory authority. If you look at the timeframe, which is Attachment A in the OIG report, if you look at the timetable there on their chart—it’s page 30 of what I have, but you may have something different—you all exercised or let them know that you might use mandatory on August 15th, and they voluntarily recalled on August 19th. So I think in response to Ms. DeGette’s question, it clearly works because you told them you were about to do it, and 4 days later, they were, like, “OK, OK, we’ll do it voluntarily.”

The problem I have is on two things that you said also in that regard. You said that part of the problem was the new technology, the whole genome sequencing. But when you look at the time chart, it raises all kinds of questions for me. So I want you to explain the whole genome in a minute.

Mr. STEARN. All right.

Mr. GRIFFITH. But here is the question that I have. There was enough information that something was going on that you all

opened up an investigation in February—late February, 6 weeks later, you actually, under using the older technology, matched an uncommon strain of Salmonella to that facility. That was on March 24th. And connected it with some of the folks who had gotten sick.

Nothing was done, apparently, at that point, there may have been some letters, I don't know. But then, the whole genome sequencing was completed on May 12th. So the discussion that you want to make sure you're doing the right thing and not disrupting, as Ms. DeGette said earlier, an entire industry with a recall that is not justified—you had that confirmation on May 12th. So May 12th, June 12th, July 12th, August 12th, all went by, eventually 3 months and a few days later you then threatened the mandatory recall.

Mr. STEARN. Right.

Mr. GRIFFITH. So the question is, the American people who are watching this, either live or later when they are having insomnia, are going to ask is, OK, we want to make sure we're doing the right thing. Maybe you can justify, although there's a question mark there between March 24th and May 12th. But once you've got the whole genome sequencing, and there's no distinguishing between the Salmonella in the sick people and in your environmental, and I know I'm not using the scientific terms, but the sick people and in the nut butter, why didn't you act then?

Mr. STEARN. So there's a number of issues that make this complicated, if I can go back a little bit.

Mr. GRIFFITH. OK.

Mr. STEARN. So there was a link under the PFGE pattern in March of 2014. It's important to understand that a couple of things—

Mr. GRIFFITH. All right now, folks back home don't know because—what is PFGE—

Mr. STEARN. This is pulsed-field gel electrophoresis. It helps link the clinical, that is, from the person, to what's happening at the facility.

Mr. GRIFFITH. Right.

Mr. STEARN. It's something that we used—been relying on for a while. It's not perfect, because it's more limited in the amount of information that—in terms of comparison of those organisms. And it shows that there's a strong link between what those organisms actually are, because something like, you know—

Mr. GRIFFITH. And that's what you linked up in March?

Mr. STEARN. That is what we linked up in March. I will tell you that our expert analysis is that was not enough to show causation at that point.

Mr. GRIFFITH. OK.

Mr. STEARN. There was no link. And it was done differently than we usually do it. Usually there's a food history that links—where they ask people, what did you eat? And they link that back. Then we look at the PFGE. That didn't happen in this case. People did something new in this case. They went through some of the data bank, and they linked that up. They linked it up with PFGE, and they linked it up with whole genome sequencing. They're very excited about that when that happened, because it does—and it actually has been something that we used that is linking up to this

database, and it's something that really is very promising. But there were delays in this case, and I should say, first of all, I think we have done better in this case.

I will tell you that when we did the whole genome sequencing, we did it for the environmentals in May. It was not until August that we linked it to the clinicals. And that was a delay in terms of doing that whole genome sequencing link, which was the trigger for that, you know, request for mandatory recall and the discussions with the firm that resulted in recall.

There were things that I think could have been done differently in this case, but I do think it's important to understand some of the complexities. This was not an obvious case on day one, and in fact, in a number of these cases, it's not obvious on day one. It's very important that we accelerate our own investigation. It's important that firms have their own investigation and their own preventative models.

But it was less than clear to the people who had that, you know, back in March because there were environmentals which were concerning, but the links to the clinicals were less than crystal clear. Like I said, it wasn't supported at that time by the food histories. And the firm tested all their products, all the products were negative. So, you know, the firm testing was—the firm was pushing back on us with some of their own testing.

The story's a little bit more complicated, but at the same time, we take the OIG's point in this, and we agree with it. We need to make sure this is—it's not OK if it takes this long, even if it's complicated. That's why we have this approach in place where we feel we need to make sure that the agency leadership and the staff are prepared to, you know, know what's a red flag and act on it to make sure we get to the right result as soon as possible.

Mr. GRIFFITH. I appreciate it and yield back.

Mr. HARPER. The gentleman yields back. The Chair will now recognize the gentlemen from New York, Mr. Tonko, for 5 minutes.

Mr. TONKO. Thank you, Mr. Chair. This committee has repeatedly heard that FDA must manage food recalls more effectively. That is why Congress gave FDA new authorities under FSMA in 2011. FDA has told us that it's taking steps to improve that recall process. However, the OIG's report finds that FDA's data on food recall is often incomplete or inaccurate, which makes it difficult, if not impossible, to tell how things have improved since Congress gave the FDA new tools.

For instance, FDA's recall data system does not track key milestones, such as the date that FDA learned that a product was potentially hazardous.

So, Ms. Jarmon, can you offer some insight about why those data are important and how incomplete data make it difficult for FDA to manage food recalls?

Ms. JARMON. Yes. It's very important that the data in their recall systems is complete and accurate. That way, they can—that's key to monitoring the food recalls. And like we mentioned in our report, there was no data in there for when FDA became aware that an item was potentially hazardous.

And so in some cases—so without having that date there, it's not possible for them to determine how long it took them from the time

they became aware that the product was potentially hazardous until the time that the food-recall initiation occurred. And in some cases, some of the longer examples that we have, like one, which was a dietary supplement, where it was 303 days from the date that FDA became aware that their product was hazardous, and actually sent a warning letter to the firm, it was 303 days later when, in that case, the food-recall initiation occurred because that date wasn't in the system. If you look at FDA system, it was 10 days based on—because the dates in the system were not correct.

Mr. TONKO. Uh-huh.

Ms. JARMON. So it's very important to make sure that the action is happening faster.

Mr. TONKO. Right. And I thank you for that. And OIG points out that because FDA doesn't record the date when it learns a product is potentially hazardous, FDA couldn't determine, for instance, that it took a firm 151 days to actually initiate a recall of hazelnuts contaminated with Salmonella. FDA claims that it would be time consuming to track this information.

Mr. Stearn, if FDA does not track milestones like this, how can you tell when firms are not moving swiftly enough to remove dangerous foods and when to take more aggressive action?

Mr. STEARN. Thank you for your question, sir. We do think it's important for the agency to record when there's a critical hazardous step. There are a number of issues in terms of our systems and how they interlink. We have different systems for different purposes and what kind of information that can be in there. We take this point, we're looking at trying to make sure that our procedures clarify and make sure that the records are correct when it has tipped over. And we're going to continue to work on that.

Mr. TONKO. Thank you. In addition to incomplete data, OIG also found that FDA did not always collect timely and complete status reports from firms during a recall.

Ms. Jarmon, does that hinder FDA's efforts to oversee the recalls, and how so?

Ms. JARMON. Yes, because it's important when—after the firm initiates the recall that the FDA is also monitoring what's happening after that period of time, so that, of course, when the initiation first started, the products are still on the shelf. So in many cases, the firm is still testing effectiveness and verifying different things related to the product. And we found, in some cases, the status reports weren't received over 100 days until after this process—the firm had been communicating their story, the recall.

So it's important that FDA continues to check on this status and monitor the firms when they're in the recall process, and the status report is one way to do that.

Mr. TONKO. Thank you. And, Mr. Stearn, does FDA agree that it needs to improve its collection of these status reports? If so, what steps do you think we should take?

Mr. STEARN. Yes, it would be—well, let me say first that we would like to have better status reports. It is entirely a voluntary process, so—it's right now and historically, and during this time, there's no obligation for a firm to provide us status reports. And we do think that that will be improved through the implementation of the preventative control rule, which requires firms to have recall

plans. And so for the first time, FDA—there will be an obligation in terms of how they conduct their recalls.

Third-party audits for recall audit checks we think are critical. We did have an extended discussion with OIG about that. We have expanded that program. That gives us a lot more flexibility, and it turns around our recall audit check process much faster. And we do think consumer notices are appropriate because it sort of jumps over the whole recall system and gets the message to where it needs to be.

Mr. TONKO. Thank you very much. Mr. Chair, I yield back.

Mr. HARPER. The gentleman yields back. The Chair will now recognize the gentlelady from Indiana, the distinguished chair of the Ethics Committee, Mrs. Brooks, for 5 minutes.

Mrs. BROOKS. Thank you, Mr. Chairman. And thank you and the ranking member for holding this important oversight hearing today. As the committee is well aware, biodefense issues are something that I've been working on. Public health securities is a top priority as we look at how we oversee our food supply. It's a security issue as well as to how it impacts a threat to our food system, that can be devastating. Much of our Nation's corn, soy, and hog supply comes from my State of Indiana. And I know and believe that our Nation needs a stronger system of monitoring animal health, both for the threats to our Nation's food supply, but also for potential outbreaks in the animal population that can mutate and jump to humans.

And should a bad actor seek to affect our food supply, our system I'm not certain is equipped to quickly determine if it's a foodborne illness naturally occurring or if it is manmade. And in the case of a bioterror attack, obviously, timely response is crucial but I know can be difficult.

So with that, Mr. Stearn, I'm interested in FDA's efforts to protect the U.S. food supply from bioterrorism or economically motivated adulteration, and what steps has the working group on economically motivated adulteration taken to improve protection of our food supply? And, more directly, so how would FDA, as we're talking about these types of food recalls coming from manufacturers, but how would FDA respond if there could possibly be a terrorist attack?

Mr. STEARN. Thank you, Ms. Brooks. There are a number of points I would make. First, there is, as part of FSMA, there's an intentional adulteration rule in which firms are to look at their own risks related to potential intentional adulteration from other parties. So there's one component.

We do have a food defense group within FDA that monitors some of the intelligence and works with some of the intelligence to try to make sure that we're able to monitor what's coming in from outside of the country, largely, in terms of food defense. And we also believe that, you know, having a preventative food safety system generally allows for closer monitoring of what's coming in and making sure that folks understand what's happening in their own supply chains. And that's the kind of danger that we've seen in some of these incidents that have happened historically, is that sometimes there's something that happens in a supply chain, and it's brought into the United States, and then we have an issue.

And the system that's being created within FSMA helps to have people monitor what's happening throughout the supply chain, which is, in part, also helpful to combat those issues.

Mrs. BROOKS. I appreciate that, but now this is as of December 2016, and here we are January 2018, the FDA—as of December 2016, so I'm curious if something has changed—the FDA still hadn't met a 2011 GAO recommendation to provide written advice to centers and offices on avenues to address economic adulteration. Has that changed? Has the FDA created a document that's been used to meet GAO's recommendation from 2011?

Mr. STEARN. I think—I'm not aware of such a document. I do know that there was a group that looked at this issue, and they found it very challenging. I've spent some of my career at FDA looking at the heparin issue for several years. I worked with the committee on that. And there are a lot of different ways that this could happen. So I think, in large part, the answer that the agency is looking for is to look at standards that get applied throughout the supply chain, because the places that we've seen this enter, the places we've seen economically adulterated products coming in, it is usually where there is a lack of accountability within the supply chain, and that's what we think is sort of the most effective strategy.

Mrs. BROOKS. And you indicate that there are a lot of, obviously, strengthening our systems against bioterror, are incredibly complex, but can you talk with us about some of the impediments and challenges that your group and those who work in that group are experiencing, so we can help break down those impediments?

Mr. STEARN. Coordination of intelligence can be a challenge. We do have a group that works with CBP at their counterterrorism center. And I would just say, just generally, that's an issue, because a lot of coordination that needs to happen, and because it is secure information that can be a challenge.

Mrs. BROOKS. I know, but we've been working on that since 9/11. And it is now 16 years later. And so you're saying that there's still a challenge with your agency working with CBP on the supply chain?

Mr. STEARN. What I would say is one of the issues that we deal with is to try to make sure the intelligence is where it needs to be. I'm not prepared to go probably any deeper than that at this point. I would say also the intentional adulteration rule is something that the agency has come out recently that does address that issue.

Mrs. BROOKS. Thank you.

I yield back. My time is up.

Mr. HARPER. The gentlelady yields back. The Chair will now recognize the gentlelady from Florida, Ms. Castor, for 5 minutes.

Ms. CASTOR. Well, thank you, Mr. Chairman and Ranking Member DeGette, for calling the hearing today. And thank you to our witnesses for the work that you're doing.

The issues we're talking about today have serious real-world consequences, as a single contaminated food product can have devastating impacts across the country, depending on what it is and how it spreads. As an example, the OIG report cited a 2014 recall of cheese products contaminated with *Listeria*. That product con-

tamination is particularly troubling because it led to one infant's death and two lost pregnancies.

According to OIG, 81 days elapsed it between FDA becoming aware of the adulterated product and the firm recalling all of the affected products. I understand that this case is particularly complex and FDA was even given misleading information from the firm. But I'd like to walk through this recall and try to shed some light on the lessons learned.

Mr. Stearn, FDA learned about the contamination on July 28th, then spent a month inspecting, testing samples, and requesting an update from the firm. You had previously mentioned that it's always important that FDA accelerate its recalls. Could you give greater detail on this case? How could FDA have shortened that phase of the recall?

Mr. STEARN. One thing I would point out, there were a number of different recall actions that took place. There were actually four different recall actions that the firm took, that Oasis took during the course of this time period that was referenced. The first was after—there was a positive sample where one of the firm's cheese products, and in less than a week, there was a recall of that particular product. And then, also, FDA initiated an inspection of the facility. So we did act quickly to follow up with that.

During the course of that inspection, there were environmental samples that were positive. We went in and did a lot of sampling in the firm. There were a number of things that were positive, and there was a frank discussion with the firm. After that, the firm made a series of promises. The firm actually—well, first, the firm said they would stop manufacturing. The firm also said that they would stop distribution until they had consulted with FDA. And the firm said that they would bring in an expert and to do additional testing. And the firm also committed to do a recall of some product—which they did initiate—that was implicated by the environmental testing positives. And so, you know, that happened. And then after that, the firm continued to manufacture at a certain point and did distribution.

Ms. CASTOR. I also understand that, after FDA conducted its test, it received a brief letter from the firm on September 11th that reportedly “lacked significant supporting documentation.” But then the firm, as you said, distributed potentially adulterated products after that, but then FDA didn't conduct another follow-up inspection until nearly a month later. Why didn't FDA take swifter action after receiving the response from the firm on September 11th?

Mr. STEARN. FDA believed the firm was not manufacturing at that time, based on what they said, and not distributing. I think that—I say that, at the same time, I say I think there's more that FDA should have done in this case. And in some respects, it gets to the issue of a preventative mindset versus reacting.

Ms. CASTOR. Because when FDA conducted its follow-up inspection on October 7th, it, again, found the presence of *Listeria*. And at this point, this was 45 days after FDA first learned about the contamination. However, it took the firm another 10 days before it voluntarily recalled all the potentially contaminated products. So at this point, what could FDA have done differently to either encourage or mandate a faster and fuller recall?

Mr. STEARN. So one of the things—and this gets back to you how some of these things can be complicated. The firm did act when FDA brought some sort of positive sample to it. They acted, they initially did a recall related to the first product sample. After there was an environmental, the firm made a series of promises which turned out to be lies, they were false. And we didn't find out fully about that until going back on inspection. But, you know, the firm said a lot of things that would be the kinds of things that FDA would want to hear: "We're going to stop manufacturing—"

Ms. CASTOR. So if they are not truthful with you or they don't follow through, how do we hold them accountable?

Mr. STEARN. I would say a couple of things. First, it is important always to verify, even this firm's recall activities should have been broader, there should have been a broader recall earlier. We had a product sample positive. We had environmental samples. We had bad practices that were documented in the firm. That is a pretty strong set. The firm made a lot of promises. The firm, I think, even given that, more should have occurred.

Ms. CASTOR. But the accountability answered.

Mr. STEARN. So in terms of it—one thing I would note is that the owner was prosecuted. FDA does have an office of criminal investigation, so that, I think, the deterrent message is important. And also, we need to verify. I mean one of the reasons, and OIG mentioned about recall audit checks and whatnot, it is very important that we do those to make sure those things happen. It is important that we have follow-up inspections to make sure what was promised gets done. So FDA has verification procedures it needs to use. And if it is a high-risk issue, like this one, we need to use them quickly.

Ms. CASTOR. Thank you. I yield back.

Mr. HARPER. The gentlelady yields back. The Chair will now recognize the gentleman from New York, Mr. Collins, for 5 minutes.

Mr. COLLINS. Yes. I thank the chairman and the witnesses. Certainly, food safety is a universal concern, and this is not a partisan hearing at all. We're genuinely trying to get to an understanding of what does happen.

So let me back off just a little. We say there's about 3,000 recalls a year, about 10 a day. Roughly how many of those are voluntary firm-initiated, and how many of those would be, you know, mandatory recalls driven by the FDA?

Mr. STEARN. Virtually all are voluntary.

Mr. COLLINS. That's what I would expect. In the threat, certainly, the mandatory is there. So since these are voluntary, whether it is under pressure or not, how quickly does the FDA classify those as a class 1, 2, or 3?

Mr. STEARN. So I think OIG referenced some of the earlier data, most recently we were doing that within 13 to 15 days in the food program.

Mr. COLLINS. And I'm assuming that, if it is class 1, you know, that's when somebody's hitting the buzzer with the red lights and so forth, that you do a lot more detailed work, analysis, urgency for a class 1.

Mr. STEARN. It is a red flag.

Mr. COLLINS. So roughly, how many class 1's a year do we get versus 2 or 3?

Mr. STEARN. I think it is in my written testimony. I would have to get back to you with the exact number.

Mr. COLLINS. But, I mean, is it 10 percent or 80 percent class 1?

Mr. STEARN. It's in between those two. So I don't have the exact number. But I'd hesitate to give a number when I'm not sure, but it is in between those. So there is a significant proportion, but it is not the majority.

Mr. COLLINS. So if it was 20 percent, that would be two a day, roughly?

Now do you have the staff that, you know, is one person given oversight of that particular recall? You've got two every day that is class 1 voluntary recalls. Is that a team that goes to work, or a single person, or—

Mr. STEARN. We have recall coordinators that are throughout the country. One of things that we've done in our recent reorganization is we specialized that staff. So there are recall coordinators who interact with the firms. There are also other components that do other things that are related to recalls. But a lot of that is run by our field staff locally.

Mr. COLLINS. So your inspectors are in these facilities every day?

Mr. STEARN. Yes.

Mr. COLLINS. Sometimes they literally have offices there.

Mr. STEARN. Yes.

Mr. COLLINS. And so we have to rely on the professional nature of the company itself. I'm thinking of the quality manual. You, I'm sure, are always reviewing the quality manuals. As you said, though, I was a little disturbed to see you don't currently mandate a recall procedure or plan? With each company that you reduce, your inspectors are not auditing recall plans today?

Mr. STEARN. Well, right now, recall plans—well, before the passage of FSMA and the implementation of preventative control rule, there was not any kind of mandate that a firm have a recall plan.

Mr. COLLINS. That would be a concern.

Mr. STEARN. So I will say when there is a recall, traditionally we will follow up, and that happened in these very cases, other cases that have traditionally happened where there is a recall. We do follow up with that on inspection, ordinarily in the next inspection to make sure, and we try to do that quickly to make sure that there's some review of what occurred.

The difference is, what's the, you know, legal requirement, what standard do they have to do? I mean, we were talking about status reports. Do they have to do status reports? What do they have to do in a recall? FSMA helps standardize that. The firm has to plan, where there is a hazard, to make sure there's some kind of plan to address recalls, in particular. Whereas before, it was more reactive.

Mr. COLLINS. I mean, common sense, if you don't have a plan, then it truly would be haphazard at best. So I would hope your inspectors who are in there every day are constantly making sure that T's are being crossed, the I's dotted.

Mr. STEARN. Thank you, Congressman. Related to your earlier question, I got a note. So we are about 1,200 products class 1 out of a little bit more than 3,600, so that's roughly a third.

Mr. COLLINS. That's actually higher than I might have expected.

Now, how often—I only have a few seconds left—does your lab do independent testing, or your labs versus relying on the company data to assess the risk?

Mr. STEARN. So we do part of the things that you mentioned in some of these where we have a class—it's where there's a certain risk profile. If it hits a certain risk profile, we will do testing in the environment of that facility. In addition, if we have reason to, we have different types of surveillance testing. We have it at import and we have it in a domestic realm, and those all go off to our labs. So we do a lot of testing ourselves. Firms also have their own testing programs.

Mr. COLLINS. Which you rely on, as well?

Mr. STEARN. That is part of our oversight, is to look at what they are doing.

Mr. COLLINS. My time's expired. I appreciate your answers. I yield back, Mr. Chairman.

Mr. HARPER. The gentleman yields back. The Chair will now recognize the gentleman from Pennsylvania, Mr. Costello, for 5 minutes.

Mr. COSTELLO. Thank you, Mr. Chairman.

Mr. Stern, as you know, the OIG report identified a number of deficiencies in the food-recall process. And I wanted to direct your attention to figure 1 that shows the days it took firms to initiate the recall after FDA learned a product was potentially hazardous, with specific reference to the new trucks research incident where it took 303 days to execute a recall after the warning letter was issued.

First, is it correct that in this particular case, it was found the firm continued passing out free samples after receiving their letter?

Mr. STEARN. I'm unsure about that specific fact.

Mr. COSTELLO. Is that easily obtainable for you to provide us in short order?

Mr. STEARN. I could.

Mr. COSTELLO. I appreciate that.

Are FDA actions, after a warning letter, typically delayed for 300 days?

Mr. STEARN. No.

Mr. COSTELLO. How often, on average, or is it customary or within the realm of accessibility, for the FDA to take an enforcement action after issuing a warning letter? What's the typical—

Mr. STEARN. There's some variation by program, I would say ordinarily we go back within 6 months. In certain areas, clinical trials, for example, it tends to be longer because there has to be enough data to actually monitor what has occurred, but this is not what ordinarily happens or what we should expect.

Mr. COSTELLO. Are the delays of a recall more of a problem with dietary supplement products?

Mr. STEARN. I would say there are—this is a good—one of the issues that occurred here in these dietary supplements, there's an ingredient, DMAA. There's some controversy about that. There has

been some litigation related to that. And I could follow up with you in some ways, but I would just say where some of the issues are scientifically challenging, the firm did challenge some of the science about the safety of the ingredient in this case.

Mr. COSTELLO. And then, final question on this line of thought: What lessons can you share that you've learned from the new trucks research case?

Mr. STEARN. I would say overall, you know, in terms of the lessons, I think we would say it's important for the agency leadership to look very closely, especially at high priority things that we've had at class 1, that is the kinds of things that have the highest risk. We need to do that prioritization, and we need to investigate, and we need to make sure that we have systems in place to act when that occurs.

Mr. COSTELLO. Were systems in place at that time and were not followed, or were the systems incomplete or insufficient?

Mr. STEARN. I think in this case, one of the issues that was related to the fact that this is not—the safety of DMAA, or the unsafety of DMAA, which the ingredient at issue there, is not—I will just say there's a controversy or different ideas about that. And, you know, to some extent, we have to resolve that sometimes in the court system.

Mr. COSTELLO. To the extent that a warning letter triggers the type of litigious activity surrounding the safety of a particular element, does that give it higher priority or does that add to the priority, or is that something within the systems that you have to address?

Mr. STEARN. I think we need to prioritize. And your question is a fair one. If we have—there are a number of warning letters that come out. The agency has a lot of different issues. If it's an issue that we find to be one that has potential harm to consumers, it's a higher risk issue, we should make sure that that gets addressed.

Mr. COSTELLO. Yes, because it strikes me that—I didn't do this kind of work as an attorney, but if you were a GC for a company, if you have a product on the market, the product is doing well, you get an FDA letter that says, "This is a warning letter," et cetera, et cetera, et cetera. Number one, I don't think a company—I wouldn't think many companies would put a product on the market that they felt was deadly or that would trigger that first tier—well, any tier, but particularly, that first tier. The question becomes, it is pretty reasonable or expectant to assume that you're going to get a response that says, "Wrong, we're going to take you to court" or "This issue is going to be litigated." And that should not freeze you up in terms of addressing what you identified as a potential health issue. So how—

Mr. STEARN. I would agree.

Mr. COSTELLO. What do you do about that?

Mr. STEARN. We need to make—again, I think, as is the kind of issue that you flagged, there may be disagreement. If it's something that the agency finds is a threat to consumers, we have to prioritize that, and we need to make sure that we bring it forward.

Mr. COSTELLO. Do you have sufficiently expansive regulatory authority in order to do that, or do you need statutory assistance?

Mr. STEARN. We are not asking for any authorities today.

Mr. COSTELLO. Very good. I appreciate your answers.

I yield back.

Mr. HARPER. The gentleman yields back. The Chair will now recognize the gentlelady from Illinois, Ms. Schakowsky, for 5 minutes.

Ms. SCHAKOWSKY. Thank you. I want to focus on FDA's mandatory recall authority. So the OIG's report describes some concerning contamination cases, and unfortunately it is not the first time we're hearing about such outbreaks. In fact, this committee has been investigating FDA's food safety efforts and recall practices for well over a decade.

Over 7 years ago, FDA told the subcommittee that mandatory recall authority would help it remove dangerous products from the market more quickly. Congress then passed the FDA Food Safety Modernization Act, FSMA, which gave FDA this very authority and significantly reformed the agency's ability to prevent and respond to outbreaks. Now we are here again discussing these issues. So I want to find out how this law is working.

Mr. Stearn, overall, has FSMA helped FDA oversee food recalls, particularly regarding inspection resources.

Mr. STEARN. Yes.

Ms. SCHAKOWSKY. So you have had enough resources in order to do the job?

Mr. STEARN. I believe we have enough resources within the—

Ms. SCHAKOWSKY. Here is then—Congress gave FDA this authority to help the agency respond to contaminated foods faster. However, the OIG reported that, between 2011 and 2016, FDA used that authority just twice. And just yesterday Commissioner Gottlieb stated, and I quote, "recall authorities and how we deploy them are a cornerstone of our vital consumer protection mission."

So Mr. Stearn, given that your recall authority is the cornerstone of the agency's consumer protection mission, can you explain why FDA has only used its mandatory recall authority twice, or a few times, anyway?

Mr. STEARN. Thank you for your question.

First, I would say our goal is to remove the product from the marketplace if it's unsafe—that we start with that as a precept. And, ordinarily, if a company is willing to do that, that's going to be the fastest way to make sure that that gets done.

Now we have a number of, as I mentioned earlier, we do think that mandatory recall is one of the things that when we get to a certain stage with a company, generally convinces that company to recall, if it's the right thing, that it does play a role in the background in our discussions as well as some of the consumer communications that the agency uses. So I would say that's really one of the things in the background, which is also to say there may be cases where it's appropriate and we should be using it if other actions aren't happening quickly enough.

Ms. SCHAKOWSKY. So the FDA has to meet certain standards before it can invoke the mandatory recall authority. Is that correct?

Mr. STEARN. That's correct.

Ms. SCHAKOWSKY. So are there difficulties in meeting that standard, or do you feel that having it there as threat is sufficient? Is that what you're saying?

Mr. STEARN. Well, what I would say is a lot of issues get into the facts, there are some complexities about identification of products sometimes and the level of hazard within products. We ordinarily don't have issues with firms when there is a pathogen in a particular lot of the product. A lot of the times that we have issues is, what about the other products made at that facility? That happened actually in the cheese recall we mentioned earlier. And what level of evidence is needed for that. So sometimes there is a question, a scientific or factual question about identification, the level of risk, and so forth.

And so those are things that I think—again, back to why we have reacted to the OIG's report the way that we have is that our centerpiece really is core, our centerpiece is to make sure that the leadership of the agency from different components, when there is a red flag, make sure we do whatever we need to do to get to the right answer quickly. When we get to the right answer, we believe we can make it happen quickly.

Ms. SCHAKOWSKY. There is some concern that FSMA has not been fully implemented and enforced. Is there anything we can do to speed up that process?

Mr. STEARN. We are actively working on FSMA implementation now. I'm very much engaged in that myself. And I don't have anything today. I can bring that back to the agency if there's anything else to add.

Ms. SCHAKOWSKY. Thank you. I yield back.

Mr. HARPER. The gentlelady yields back. The Chair will now recognize the gentleman from Georgia, Mr. Carter, for 5 minutes.

Mr. CARTER. Thank you. And thank both of you for being here. This is obviously a very important subject, particularly for us in the State of Georgia. As you know, we had the unfortunate incident some years ago with the peanuts, and that's still fresh in our minds.

Mr. Stearn, let me ask you, when you released the updated guidance yesterday on accelerating the recall process, part of it included the FDA to step in if a company hadn't sufficiently addressed a recall. How do you determine if they sufficiently addressed it or not?

Mr. STEARN. Right. So the guidance yesterday we released talks about public warning and notification. It talks about when we think a company should issue a warning, and we describe how that should be done, and when FDA will issue public warnings, as well as some changes in notification. This goes back to the issue we were talking about earlier in terms of, you know, FDA has to get to the right answer in terms of evaluating the issue as soon as possible. So if we understand the issue, we think it's best when we have a consistent message with a company that's responsible. There's not dueling messages, it's clear and that's what we—

Mr. CARTER. How often does that happen, that you have dueling messages?

Mr. STEARN. I would say the overwhelming number of times we can get to the right answer, you know, in terms of our communications with a company. There are times where—and it's not the usual case.

Mr. CARTER. Is the right answer always your answer or—

Mr. STEARN. I'm sorry?

Mr. CARTER. Is the right answer always your answer, or does the company—

Mr. STEARN. Well, we do have a dialogue with companies, I mean, we do listen to them, and some companies have—I have been engaged in a number of technical conversations where a company has said things that have changed our minds, so that does happen. Sometimes we're dealing with a company, though, where they don't understand the problem. We need to get a message to consumers, and if they are not willing to do that, we have to be willing to do that.

Mr. CARTER. If that is the case, sir, there are repercussions for that company?

Mr. STEARN. So ordinarily, I mean, most of our recalls, the firm prepares a press release, we comment on that press release. We want to make sure it is actionable for consumers. If a firm will not or cannot do that, the FDA will, or if we think that it is appropriate even when a firm has done it, because we will have to reach a certain population or there's a way to do it that we think is necessary, FDA will issue its own consumer communication.

Mr. CARTER. You issue it, are there any penalties to the company?

Mr. STEARN. Oh, to the company? No.

Mr. CARTER. If you have to step in and you have to exert that energy, and you have to exert that authority, there ought to be ramifications.

Mr. STEARN. Right. I do think—one of the things I go back to, which is not fully developed, but under the preventative control rule within FSMA, firms have to have their own recall plan, and—

Mr. CARTER. Is that approved by FDA? The recall plan?

Mr. STEARN. Well, it is not formally approved. But it is, I say, when we go in, we have to have oversight responsibility, so they have some obligation to do it, and we could exercise some regulatory oversight if the firm did not act appropriately in that regard.

Mr. CARTER. OK. Let me ask you, in December, the inspector general's office of HHS released a report on food recall, the process. And understand when the FDA learned that a product was potentially hazardous, FDA stated that "tracking this data for all recalls would be time consuming and difficult, as the data may be located in different FDA systems or obtained from sources outside of FDA." What kind of sources outside of FDA are you talking about?

Mr. STEARN. Well, we may get information, I mean, we work with States a lot, so sometimes States have their own—there's a lot of State inspections that States may find a food safety issue that they communicate to us. Sometimes we have information that comes from foreign governments. Sometimes we have information that comes from third-party sources.

Mr. CARTER. If that's information that is concerning, is there a time when the State feels like the FDA needs to know this, they send you that information?

Mr. STEARN. Yes, that happens. In fact, it happened in one of these cases. You know, we worked with Virginia. Virginia did some testing that kicked off the cheese recall we were discussing earlier.

Mr. CARTER. So you feel like you have all the information that you need? That's the question, because I know you can't make a decision until you've got all the information.

Mr. STEARN. I think I would just say one of the challenges that we have—and I think it is a challenge—is that we deal with thousands of firms, and there are a lot of different food safety issues. These days, we are also getting information from different sources, and that, in fact, happened in these cases. And we need to find—we take the point, we need to find a way, it is part of the question is how, we need to find a way to make sure that we get all the relevant information in as soon as possible to make sure we get to the right answer. We take that point.

I think, technically, there are some challenges, there are some challenges within our data systems, we have a lot of different ones.

Mr. CARTER. Is there anything we can do to assist you with that?

Mr. STEARN. I would have to take that back to the agency.

Mr. CARTER. OK. Know that we are ready and willing. OK? Thank you for the work that you do. It is extremely important, both of you. Thank you very much.

Mr. STEARN. Thank you, sir.

Mr. CARTER. And I yield back.

Mr. HARPER. The gentleman yields back. I want to thank you, Ms. Jarmon, and you, Mr. Stearn, to shed some light on where we are and recognizing the importance of this issue, and we appreciate you being here today. I remind Members that they have 10 business days to submit questions for the record. I ask that the witnesses agree to respond promptly to any questions that are submitted.

With that, this subcommittee's adjourned.

[Whereupon, at 10:30 a.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

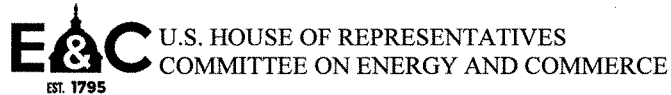
PREPARED STATEMENT OF HON. MICHAEL C. BURGESS

Today we continue our examination of food safety—a matter which has been of interest to the American public ever since the publishing of Upton Sinclair's "The Jungle" in 1906. The Food and Drug Administration's (FDA) ability to ensure the safety of our food supply is an issue that affects every grocery store, restaurant, school, and home in America.

The passage of the FDA Food Safety Modernization Act in December 2010 was a step in the right direction, giving FDA greater authority to regulate, inspect, and recall food when necessary. However, the recent report from the Office of Inspector General at the Department of Health and Human Services concluded that there is still work left to do.

Mr. Chairman, thank you for holding this hearing. Also, thank you to our witnesses for being here today. I look forward to your testimony.

I yield back.



January 17, 2018

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled "Safety of the U.S. Food Supply: Continuing Concerns Over the Food and Drug Administration's Food-Recall Process."

The Subcommittee on Oversight and Investigations will hold a hearing on Friday, January 19, 2018, at 9:00 a.m. in 2123 Rayburn House Office Building. The hearing is entitled "Safety of the U.S. Food Supply: Continuing Concerns Over the Food and Drug Administration's Food-Recall Process."

This hearing will examine a December 2017 report by the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG). The report identified a number of deficiencies in the U.S. Food and Drug Administration's (FDA) food recall process, including that FDA could not always ensure that firms initiated recalls promptly and that FDA did not always evaluate health hazards in a timely manner; issue audit check assignments at the appropriate level; complete audit checks in accordance with its procedures; collect timely and complete status reports from firms that have issued recalls; track key recall data in their electronic system; and maintain accurate recall data in the electronic data system. The purpose of the hearing is to determine the reasons for the identified deficiencies, to what extent the FDA Food Safety Modernization Act (FSMA) has improved FDA's oversight of food recalls since its passage in 2011, and what actions the FDA is taking to implement the report's recommendations or to address the deficiencies.

I. WITNESSES

- Gloria Jarmon, Deputy Inspector General for Audit Services, HHS Office of Inspector General; and,
- Douglas Stearn, Office of Regulatory Affairs, Director, Office of Enforcement and Import Operations, Food and Drug Administration.

II. BACKGROUND

A. Estimates of health and economic impact from foodborne illness

In this decade, the Centers for Disease Control and Prevention (CDC) estimates that each year roughly one in six Americans (or 48 million people) gets sick, 128,000 are hospitalized, and 3,000 die of foodborne illness.¹ CDC data also show that the number of reported multistate

¹ CDC, Estimates of Foodborne Illness in the U.S., *available at* <https://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html>.

Majority Memorandum for January 19, 2018, Subcommittee on Oversight and Investigations Hearing
Page 2

foodborne illness outbreaks is increasing over the past decade.² According to the Government Accountability Office (GAO), this is notable because although multistate outbreaks make up a small proportion of total outbreaks, they affect greater numbers of people.³

Most who get sick from a foodborne illness will recover without any lasting effects; however, some individuals may suffer long-term health effects, such as kidney failure, chronic arthritis, or nerve damage.⁴ According to a May 2015 estimate from the U.S. Department of Agriculture's (USDA) Economic Research Service, the 15 most common foodborne pathogens together impose an economic burden related to foodborne illnesses, hospitalizations, and deaths in the United States of over \$15.5 billion annually.⁵ In 2015, FDA researchers estimated that health costs associated with foodborne illness are approximately \$36 billion annually.⁶

In addition to the human health toll, foodborne illness outbreaks can impose high costs to industry from food recalls.⁷ A study published by the Grocery Manufacturers Association (GMA), surveying 36 GMA member companies, found that more than half had been affected by a product recall in the prior five years.⁸ Based on the survey results, the four largest costs that companies face as a result of a recall are business interruption or lost profits; recall execution costs such as destroying and replacing recalled products; liability risk; and company or brand reputation damage.

B. FDA authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act) was passed by Congress in 1938 and gives authority to the FDA to oversee the safety, of food, drugs, and cosmetics. The FD&C Act "requires FDA to safeguard the Nation's food supply, including dietary supplements, and ensure that all ingredients are safe."⁹ The FDA's Center for Food Safety and Applied Nutrition (CFSAN) and the FDA's Office of Regulatory Affairs (ORA) work together to oversee food recalls. The ORA district offices are responsible for overseeing recalls for any companies or

² CDC List of Selected Multistate Foodborne Outbreak Investigations, *available at* <https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html>.

³ U.S. GAO – High Risk: Improving Federal Oversight of Food Safety, (2017), *available at* https://www.gao.gov/highrisk/improving_federal_oversight_food_safety/why_did_study.

⁴ *Id.*

⁵ U.S. Department of Agriculture, Economic Research Service, Economic Information Bulletin Number 140, Economic Burden of Foodborne Illnesses Acquired in the United States, (May 2015), *available at* https://www.ers.usda.gov/webdocs/publications/43984/52807_eib140.pdf.

⁶ Travis Minor, et al., The Per Case and Total Annual Costs of Foodborne Illness in the United States, 35 Risk Analysis 1125 (June 2015), *available at* <http://onlinelibrary.wiley.com/doi/10.1111/risa.12316/abstract;jsessionid=BB1C19DE0558F076C9D49E994F582A30.f01t01>.

⁷ *Id.*

⁸ GMA, Covington & Burling, and Ernst & Young, Capturing Recall Costs: Measuring and Recovering the Losses, (2011), *available at* http://www.gmaonline.org/file-manager/images/gmapublications/Capturing_Recall_Costs_GMA_Whitepaper_FINAL.pdf.

⁹ Department of Health and Human Services Office of Inspector General, *The Food and Drug Administration's Food-Recall Process Did Not Always Ensure the Safety of the Nation's Food Supply*, (Dec. 2017), *available at* <https://oig.hhs.gov/oas/reports/region1/11601502.pdf>.

Majority Memorandum for January 19, 2018, Subcommittee on Oversight and Investigations
Hearing
Page 3

“firms” where a recalling firm is located and therefore are responsible for providing guidance to the recalling firms and monitoring day-to-day activities related to the recalls.

In January 2011, FSMA was signed into law. This law gives the Secretary of HHS authority to conduct mandatory recalls and assess and collect fees related to food facility re-inspections and food recall orders. FSMA “aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.”¹⁰ In order for FDA to use its mandatory recall authority, FDA must determine that there is a reasonable probability that the food is adulterated or misbranded and that it will cause serious adverse health consequences or death to humans or animals. To date, FDA has initiated the process to use its mandatory recall authority twice; once in February 2013 and once in November 2013.¹¹

“A recall is a firm’s removal or correction of a marketed product that FDA considers to be in violation of the FD&C Act and against which FDA would initiate a legal action (e.g., seizure).”¹² Corrections may include repair, modification, adjustment, relabeling, destruction, or inspection of a product without its physical removal to some other location.¹³ Food recalls are the most effective means of protecting public health when a widely consumed food product is either defective or potentially harmful.¹⁴

FDA completes a health hazard evaluation (HHE) for each recall, which is used to classify the recall and assess the firm’s recall strategy. A recall may be classified as Class I, II, or III. In Class I recalls, there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.¹⁵ In Class II recalls, the use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or the probability of serious adverse health consequences or death is remote.¹⁶ In Class III recalls, the use of or exposure to a violative product is not likely to cause adverse health consequences.¹⁷

C. Recent audits before the 2017 OIG Report

Prior to the 2017 report and the enactment of FSMA, OIG had issued two audits related to FDA food recalls. In 2009, the OIG reviewed the FDA’s monitoring of pet food recalls.¹⁸ Among the deficiencies noted, the OIG found: FDA did not always follow its procedures in

¹⁰ U.S. Food & Drug Administration, FDA Food Safety Modernization Act (FSMA), available at <https://www.fda.gov/Food/GuidanceRegulation/FSMA/>.

¹¹ OIG report, *supra* note 9.

¹² *Id.* at 2.

¹³ GAO, Food Safety: FDA’s Food Advisory and Recall Process Needs Strengthening, GAO-12-859, (July 2012), available at <https://www.gao.gov/assets/600/593031.pdf>.

¹⁴ OIG report, *supra* note 9 at 1.

¹⁵ 21 CFR § 7.3.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ Department of Health and Human Services Office of Inspector General, *The Food and Drug Administration’s Monitoring of Pet Food Recalls*, A-01-07-01503, (Aug. 2009), available at <https://oig.hhs.gov/oas/reports/region1/10701503.pdf>.

Majority Memorandum for January 19, 2018, Subcommittee on Oversight and Investigations
Hearing
Page 4

overseeing three of the five recalls reviewed; FDA's procedures were not always adequate for monitoring large recalls; occasional lax adherence by FDA to its recall guidance and internal procedures and the inadequacy of some of those procedures; and limited FDA ability to ensure that contaminated pet food was promptly removed from retailers' shelves.

In 2011, the OIG reviewed the FDA's monitoring of imported food recalls.¹⁹ The OIG's review found that FDA's guidance for developing and implementing food recalls was not adequate to ensure the safety of the Nation's food supply because it was not enforceable. In addition, FDA did not always follow its own procedures for ensuring that the recall process operated efficiently and effectively. Among its observations, the OIG found that FDA did not always conduct timely and complete audit checks of consignees, or did not review recall strategies and promptly issue notification letters to firms conveying the review results and other essential instructions.

The GAO also raised concerns about FDA's food recall process in 2012, noting that FDA faced a number of communication challenges when advising the public about food recalls or outbreaks of foodborne illness.²⁰ In addition, in 2017, the GAO continued to include federal oversight of food safety on the high-risk list.²¹ Improving federal oversight of food safety has been on GAO's high-risk list since 2007.²²

D. HHS OIG Early Alert

The HHS OIG started its review of FDA's food-recall process in early 2015, with field work starting in April 2015.²³ In June 2016, HHS OIG issued an Early Alert memorandum to FDA on a preliminary finding from its ongoing audit. The early alert raised concerns that FDA did not have adequate policies and procedures to ensure that firms take prompt and effective action in initiating voluntary recalls.²⁴ Two months earlier, the FDA established a team of senior leaders to make decisions in the most challenging food recall cases.²⁵ The team is called SCORE (Strategic Coordinated Oversight of Recall Execution).²⁶ FDA's hearing witness, Douglas Stearn, is a co-leader of SCORE. According to FDA, SCORE has reviewed and directed a large number of operations in the most difficult cases that FDA faced during the April 2016 – October 2017 time period.²⁷ The agency believes SCORE has made a difference in

¹⁹ U.S. Department of Health and Human Services, Office of Inspector General, *Review of The Food and Drug Administration's Monitoring of Imported Food Recalls*, A-01-07-01503, (Aug. 2009), available at <https://oig.hhs.gov/oas/reports/region1/10701503.pdf>.

²⁰ U.S. Government Accountability Office, *Food Safety: FDA's Food Advisory and Recall Process Needs Strengthening*, GAO-12-589, (July 2012), available at <https://www.gao.gov/assets/600/593031.pdf>.

²¹ U.S. Government Accountability Office, *High Risk Series: Progress on Many High-Risk Areas, While Substantial Efforts Needed on Others*, GAO-17-317, (Feb. 2017), available at <https://www.gao.gov/assets/690/682765.pdf>.

²² GAO, *High-Risk Series: An Update*, GAO-07-310, (Jan. 2007), available at <https://www.gao.gov/assets/260/255951.pdf>.

²³ OIG Report, Appendix C: Audit Scope and Methodology, *supra* note 9 at 32.

²⁴ OIG report, *supra* note 9.

²⁵ FDA Comments (Oct. 6, 2017), Appendix J to HHS OIG Dec. 2017 report.

²⁶ *Id.*

²⁷ *Id.*

Majority Memorandum for January 19, 2018, Subcommittee on Oversight and Investigations
Hearing
Page 5

ensuring that FDA acts quickly to investigate and reduce consumer exposure to potentially harmful foods on the market.²⁸ FDA also has recently initiated a new quality systems audit process and a plan to provide earlier notice to the public and more guidance to staff.²⁹ HHS OIG acknowledged that the Early Alert memorandum and its review spurred major changes in FDA's oversight of the process, but maintained the recommendations in the Early Alert memorandum in the report.³⁰

E. HHS OIG December 2017 Report

The HHS OIG audit covered 30 voluntary food recalls (23 Class I and seven Class II) "judgmentally" selected by the OIG from the 1,557 food recalls reported to FDA between October 1, 2012, and May 4, 2015. The OIG focused on FDA's (1) oversight of firms' initiation of food recalls, (2) monitoring of firm-initiation of food recalls, and (3) maintenance of food-recall data in the electronic recall data system. The OIG report found deficiencies in each of these areas.

The OIG found:³¹

- *FDA could not always ensure that firms initiated recalls promptly.* The 30 voluntary recalls reviewed had a median of 29 days to initiate, with an average of 57 days. Initiation of these recalls ranged from nine days before to 303 days after FDA learned that the product was potentially hazardous. The timeliness of recalls depended on how quickly firms chose to respond to safety information, whether FDA and the firm disputed the lawfulness of a product, or whether the firm lied to FDA about suspending manufacture and distribution of a product. Recalls were not always initiated promptly because FDA did not have adequate procedures to ensure that firms take prompt and effective action in initiating voluntary recalls.
- *FDA did not always evaluate health hazards in a timely manner.* For the 14 recalls that the OIG could evaluate for timeliness, the median working days to complete the HHE after learning of a planned or in-progress recall was 27 working days, with an average of 47 days. There were three reasons for FDA not completing some HHEs in a timely manner: (1) FDA did not always follow the 24-hour timeframe in its procedures for submitting the recall alert to an electronic data system called the Recall Enterprise System (RES) after learning of a firm's decision to recall; (2) FDA sometimes had difficulties obtaining necessary information for decisions about the seriousness of the health hazard because the firm's lack of responsiveness or the firm's own difficulties obtaining information; and (3) FDA's interim mandatory recall procedures did not include factors to consider when determining the existence of a reasonable probability that a food would cause serious adverse health consequences or death.

²⁸ *Id.*

²⁹ *Id.*

³⁰ OIG report, *supra* note 9, at 4.

³¹ OIG report, *supra* note 9.

Majority Memorandum for January 19, 2018, Subcommittee on Oversight and Investigations
Hearing
Page 6

- *FDA did not always issue audit check assignments consistent with the level of the proposed audit program.* A recall “audit check” is a visit, telephone call, or letter from FDA staff to a consignee to verify that the consignee has been notified of the recall, and has taken appropriate action.³² For 19 of the 27 recalls, the FDA monitoring district office issued audit check assignments at the level of the proposed audit program. For the remaining eight recalls, fewer audit checks were issued than what was required for the level in the proposed program. FDA did not always issue audit checks at assigned levels or based on accurate distribution information because FDA recall coordinators (1) had insufficient oversight to ensure that the assignment was at the appropriate level or (2) obtained incomplete or inaccurate information from the firm.
- *FDA did not always complete audit checks in accordance with procedures.* For 21 of the 25 audit checks that were conducted in the OIG sample, FDA did not complete the last audit check within 20 days of issuance of the firm’s recall communication. For these 21 recalls, the median days for FDA to finish the audit check after the firm issued its recall communication was 69 days, with an average of 118 days. The OIG noted that FDA did not retain a third-party contractor to assist with audit checks despite limited staff resources. The OIG also observed that the FDA staff did not always provide regular updates to the recall coordinator and that the recall coordinators did not always follow up with district offices to ensure that audit checks were completed in a timely manner. None of the FDA data systems could be used to assist staff with tracking results of audit checks.
- *FDA did not always collect timely and complete status reports from recalling firms.* For 11 of the 30 recalls, FDA either did not request or collect status reports. For the remaining 19 recalls, the median days for FDA to collect the first status report was 122 days, with an average of 143 days. In addition, for the 19 recalls in which at least one status report was provided, five did not contain complete effectiveness check information. FDA’s procedure for collecting timely and complete status reports was inadequate because the procedures did not require staff to request status reports at the time the recall was initiated. FDA also did not always include the request for status reports in the recall notification letter or follow up with firms when the status reports were not provided, provided late, or were incomplete.
- *FDA did not track key recall data in the electronic recall enterprise system.* FDA did not have established performance measures and indicators to track key milestones of the food-recall process, in accordance with federal internal control standards. In addition, the FDA RES data system did not track all information necessary for FDA to effectively monitor recall activities and assess the timeliness of recalls. For example, FDA could not use the RES to calculate that it took 151 days to initiate the recall of hazelnuts contaminated with *Salmonella*.

³² FDA 2017 Investigations Operations Manual, chapter 7.3.2.1, available at <https://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123513.pdf>.

Majority Memorandum for January 19, 2018, Subcommittee on Oversight and Investigations
Hearing
Page 7

- *FDA did not always maintain accurate recall data in the recall enterprise system.* For 11 of the 30 recalls (37 percent), the RES contained an inaccurate recall initiation date, which was off by a median of four days and an average of 16 days. FDA's RES User Manual did not clearly define the term "recall initiation" date, and therefore, FDA staff input other dates into the RES. Finally, FDA did not have a data quality assurance process to help ensure that RES data was accurate and complete.

As a result of these findings, the OIG issued 14 recommendations to FDA. The OIG recommended that FDA:

- Establish set timeframes, through its SCORE initiative, for FDA to (1) discuss the possibility of a voluntary recall with a firm and (2) initiate its use of its mandatory recall authority;
- Include in its recall audit plan a step to monitor when the recall alert was submitted to the RES, and if appropriate, take steps to encourage submission of the recall audit plan to the RES as soon as possible;
- Finalize its interim mandatory recall procedures and consider issuing guidance for FDA staff on factors that should be considered in determining a reasonable probability that a food could cause a serious adverse health consequence or death;
- Ensure, through its recall audit plan, that audit checks are issued at the level specified in the FDA audit program;
- Develop procedures to ensure FDA uses complete and accurate distribution lists when assigning audit checks;
- Increase the use of third-party audits through its recall strategic plan;
- Ensure through its recall audit plan that FDA audit checks follow procedures;
- Improve audit check tracking and monitoring using the RES or another FDA system;
- Implement procedures to request status reports at the initiation of the recall and ensure follow-up with firms that do not provide timely or complete status reports;
- Develop a policy for defining and a procedure for identifying retrospectively the date that FDA learns of a potentially hazardous product;
- Establish performance measures for the length of time between the date FDA learns of a potentially hazardous product and the date a firm initiates a voluntary recall;
- Clarify the definition of "recall initiation date" in its policies and procedures;

Majority Memorandum for January 19, 2018, Subcommittee on Oversight and Investigations
Hearing
Page 8

- Develop and implement a data quality assurance process to ensure that the RES contains accurate information; and
- Consider the results of the OIG review when implementing recent SCORE initiatives.

F. FDA comments

FDA agreed with the OIG's conclusion that it needed to help ensure that recalls are initiated promptly in all circumstances and said that it will consider the results of the OIG review as it "continues to operate the SCORE team." FDA also described actions it took in response to the OIG's June 2016 Early Alert. Although FDA has claimed that the OIG's recall sample was an "extreme outlier," FDA Commissioner Scott Gottlieb has stated that "[e]ven just a handful of problematic recalls are too many, because lives are at stake."³³ Dr. Gottlieb also stated that the FDA agreed that in some situations identifying the retail stores not just the food manufacturer and distributor would help, and the agency is looking into the collection and release of this information.³⁴ In addition to the issues identified by the OIG, the FDA through its SCORE initiative is also identifying approaches for improving the timeliness of its food recall process.

Although there have been only two mandatory recalls since FSMA was enacted, the FDA told bipartisan committee staff that it believed the mandatory recall authority improved FDA's leverage during recall discussions with firms and was helpful to industry response since the law provided a legal foundation for the firm's role in recalls.³⁵ FDA also told staff that the FDA laboratories, primarily ORA laboratories, provide sample-testing that can be part and a critical component of the HHE.³⁶ However, FDA acknowledged that there are issues with turnaround time in getting test results from the labs.³⁷

Regarding oversight of training, scientific capability, and safety of labs, the FDA, partly in response to the Oversight and Investigations Subcommittee's April 2016 hearing on federal select agents,³⁸ established the FDA Office of Laboratory Science and Safety (OLSS). In accordance with the recommendations of an external federal working group and the model followed by the CDC, the OLSS is located in the Office of FDA Commissioner with the OLSS Director being a direct report to the Commissioner. However, FDA is not yet completely following the working group recommendation and the CDC model because it has not established

³³ FDA Commissioner Scott Gottlieb, "FDA: We're working to protect consumers," USA Today (Jan. 2, 2018), available at <https://www.usatoday.com/story/opinion/2018/01/02/fda-working-protect-consumers-editorials-debates/109104418/>.

³⁴ *Id.*

³⁵ FDA briefing with bipartisan Committee staff, Jan. 12, 2018. FDA staff also stated that FDA is not requesting additional authority.

³⁶ *Id.*

³⁷ *Id.*

³⁸ How Secure Are U.S. Bioresearch Labs? Preventing the Next Safety Lapse, Hearing before the House Energy and Commerce Subcommittee on Oversight and Investigations (April 20, 2016), available at <https://energycommerce.house.gov/hearings/how-secure-are-us-bioresearch-labs-preventing-next-safety-lapse/>.

Majority Memorandum for January 19, 2018, Subcommittee on Oversight and Investigations
Hearing
Page 9

a dedicated and independent source of funding for OLSS and a permanent staff for OLSS.³⁹ Instead, OLSS is being supported by funding from the FDA Centers and relies temporarily on detailees for staffing. FDA is still working to establish the long-term funding for OLSS. As a result, it appears that the FDA OLSS has not conducted any GAO-recommended⁴⁰ annual inspections of the FDA labs during the last two years.⁴¹

III. ISSUES

The following issues may be examined at the hearing:

- What is FDA doing to ensure that recalls are initiated promptly?
- How does FDA plan to improve the audit check process?
- How does FDA plan to better track and maintain accurate recall data in their electronic data system?
- What impact has FSMA had on the FDA food-recall process?
- How does the HHS OIG plan to follow-up in its next audit to determine whether the FDA has implemented the OIG recommendations and is making progress with the food-recall process?

IV. STAFF CONTACTS

If you have any questions regarding the hearing, please contact Alan Slobodin, Brittany Havens, or Jen Barblan of the Committee staff at (202) 225-2927.

³⁹ Email from FDA Office of Legislative Affairs to Committee Staff, (Aug. 30, 2017), (“In FY 2017, OLSS recruited 19 individuals through temporary detail assignments and contract support, but did not hire any permanent FTEs. . . . Absent a direct appropriation for OLSS in FY 2018, OLSS will not be funded through a central source, and instead FDA will identify an appropriate method to utilize funding Congress provides the agency to support the lab safety program. One possibility being considered is allocating costs across FDA Centers based on the level of support OLSS will provide to their lab programs.”).

⁴⁰ U.S. Government Accountability Office, *High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety*, GAO-16-305, (March 2016), *available at* <https://www.gao.gov/assets/680/675925.pdf>.

⁴¹ Email from FDA Office of Legislative Affairs to Committee Staff, December 6, 2017 (“Regarding annual inspections, which are currently performed by FDA Centers and ORA, FDA is providing a standardized process to support this work. To further strengthen the process, OLSS intends to conduct audits of the inspection reports being produced by the centers.”).

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641

February 7, 2018

Ms. Gloria Jarmon
Deputy Inspector General
Audit Services
Office of Inspector General
Department of Health and Human Services
330 Independence Avenue, S.W.
Washington, DC 20201

Dear Ms. Jarmon:

Thank you for appearing before the Subcommittee on Oversight and Investigations on January 19, 2018, to testify at the hearing entitled "Safety of the U.S. Food Supply: Continuing Concerns Over the Food and Drug Administration's Food-Recall Process."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Wednesday, February 21, 2018. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Ali.Fulling@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Gregg Harper
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

Gloria L. Jarmon, Deputy Inspector General for Audit Services, Office of Inspector General, U.S. Department of Health and Human Services, response to questions for the record following "Safety of the U.S. Food Supply: Continuing Concerns Over the Food and Drug Administration's Food-Recall Process."

**U.S. House Subcommittee on Oversight and Investigations, Committee on Energy and Commerce
"Safety of the U.S. Food Supply: Continuing Concerns Over the Food and Drug Administration's
Food-Recall Process"**

January 19, 2018

Questions for the Record

The Honorable Gregg Harper

- 1. What was the total number of voluntary Class I food recalls reported to FDA between October 1, 2012, and May 4, 2015 - i.e. the timeframe in which you picked the sample of recalls in which you focused on in the OIG's report?**

There were 679 voluntary class I food recalls during our timeframe. In addition, there were 121 food recalls that were not yet classified as of the time we received data from FDA. A portion of these 121 food recalls would likely have been classified as class I.

The Honorable Michael C. Burgess

- 1. Technology and data are revolutionizing many businesses and markets throughout our society and economy, but in order to take advantage of their power, we need to ensure that the data being shared is accurate. The HHS OIG report highlights that FDA's data collection and sharing has been hindering timely and effective food recalls. What steps is FDA taking to improve its data input and collection and to incentivize companies to share information in a timely manner?**

We defer to FDA to address steps being taken in response to our report. FDA has 6 months after OIG issues the final report to provide a management decision on all open recommendations. If FDA has completed action on a recommendation, it should provide evidence to OIG to review. OIG then reviews the update and determines whether the recommendation should be closed. In some instances in which new processes and procedures are put in place, OIG conducts a followup audit to determine whether the action taken has adequately addressed the finding.

2. **The HHS OIG report outlines concerns surrounding the inaccuracy or incompleteness of information that companies provide to the FDA. Specifically, in a nut butter product case involving a *Salmonella* contamination, the firm was reluctant to provide FDA with information necessary to complete the Health Hazard Evaluation (HHE). To what extent can FDA engage with these companies to incentivize them to provide correct information in a timely manner? Are companies aware they are providing FDA with faulty information, or do you anticipate that their method of data collection is flawed?**

Our report focused on FDA's oversight of the food recall process. As such, we reviewed FDA's recall records and interviewed relevant FDA staff. We found that FDA may request additional information from a firm if FDA identifies inconsistencies in the firm's information. However, FDA generally relies on the information that recalling firms provide. We did not conduct site visits at recalling firms or interview recalling firms' personnel to discuss what information the firms provide to FDA during a recall or whether that information is complete and accurate. Therefore, we cannot determine whether recalling firms are aware that they are providing FDA with faulty information or whether their data collection methods are flawed.

We note that sections 414(a) and 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by section 101 the FDA Food Safety Modernization Act, authorize FDA to access and copy records relating to certain harmful foods. Section 10-4 of FDA's Regulatory Procedures Manual describes the authority, criteria, and procedure for inspecting records under these sections. Firms may not refuse to permit access to or copying of records requested under section 414 of the FD&C Act (section 301(e) of the FD&C Act).

3. **You outlined in your written testimony that the methodology of this review included a sample of thirty FDA food recalls between a three-year period. How were these thirty recalls selected for review?**

a. Do you feel they are an accurate sample of the issues noted in your testimony?

Our audit covered 30 voluntary food recalls (23 Class I and 7 Class II) judgmentally selected from the 1,557 food recalls reported to FDA between October 1, 2012, and May 4, 2015. We selected recalls based on risk factors related to the timing of the recall and other risk factors. Timing-related risk factors included how long it took to initiate the recall, when the firm began notifying its distribution chain of the recall, when the firm issued a press release, how long it took to classify the recall, how long it took to complete the recall, and how long it took to terminate the completed recall. Other risk factors included the level of FDA's involvement in the initiation of the recall (i.e., firm-initiated, State-initiated, or FDA-initiated), the scope of the recall (i.e., depth of recall, number of consignees, number of days the product was manufactured, and number of days the product was distributed), the reason for the recall, the classification of the recall, and media coverage.

The 30 recalls selected for review are an accurate sample of the issues noted in our testimony. Because we selected a judgmental sample, the sample results are informative about deficiencies in FDA's food-recall oversight process, but may not be representative of the full population of FDA recalls.

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

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COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641
February 7, 2018

Mr. Douglas Stearn
Director
Office of Enforcement and Import Operations
Office of Regulatory Affairs
U.S. Food and Drug Administration
12420 Parklawn Drive
Rockville, MD 20857

Dear Mr. Stearn:

Thank you for appearing before the Subcommittee on Oversight and Investigations on January 19, 2018, to testify at the hearing entitled "Safety of the U.S. Food Supply: Continuing Concerns Over the Food and Drug Administration's Food-Recall Process."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Wednesday, February 21, 2018. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Ali.Fulling@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Gregg Harper
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

[Mr. Stearn did not answer submitted questions for the record by the time of printing.]

Attachment—Additional Questions for the RecordThe Honorable Gregg Harper

1. How many food recalls did FDA issue last year?
 - a. What about over the past 3 years?
2. What was the total number of voluntary Class I food recalls reported to FDA for each of the last three fiscal years?
 - a. How many mandatory Class I food recalls in each of the last three fiscal years?
3. What is the average time it takes FDA to initiate a Class I food recall?
4. Are food recalls taking the appropriate length of time to initiate and complete?
 - a. If not, what needs to be done to speed up the process?
5. In OIG's June 2016 Early Alert, the OIG concluded that FDA should set timeframes for FDA to request a voluntary recall and for firms to initiate the voluntary recall. OIG still included that recommendation in this report. Why didn't FDA do that after the Early Alert in June 2016?
 - a. Has FDA since implemented that recommendation? If yes, how and when? If not, does FDA plan to and is there a timeframe?
6. What kinds of tests do FDA labs conduct in support of a food-related recall? What are the estimated number of samples tested by FDA labs each year?
7. Do most of these laboratory tests take place in FDA's Office of Regulatory Affairs (ORA) labs or FDA's labs in its Center for Food Safety?
8. How long does it take for FDA laboratories to conduct the test once the food arrives in the laboratory?
9. Does FDA have concerns about the turnaround time in getting test results from the labs?
10. Does FDA collect information from the labs such as the type of test, date sample received, date test completed, date notification of recall was issued etc.?
 - a. If so, does FDA look at this information, and if so, has FDA assessed the timeliness of FDA lab testing and communication of the results? What does it show over the past year?
11. How long does it take the FDA to issue a recall notice once the laboratory testing has been concluded?
12. Are there specific validated test protocols at FDA to support the testing to evaluate health hazards in a food recall? How does FDA know it is getting valid test results from its labs?
13. When were these testing protocols developed and by whom?

14. How many new protocols have FDA developed and validated to stay abreast of advancement in science and to reduce the time line for testing results?
15. The case involving contaminated products from the Peanut Corporation of America, the subject of a February 2009 hearing before this Subcommittee, showed that FDA will occasionally confront a lawless or uncooperative company in a food safety investigation. The OIG report highlights cases where the FDA's recall process was impeded or delayed by uncooperative or dishonest companies. One case that comes to mind, Oasis Brands, involved cheese products contaminated with listeria, and the owner continued to have his company ship cheese with listeria even though he had told, and therefore misled the FDA, about suspending deliveries. Some recalls were delayed up to 81 days in part because of this deception. What can FDA investigators do to detect lying and deception sooner?
16. According to the OIG report, an adulterated dietary supplement product was not recalled until 303 days after a warning letter was issued because the FDA and the company disagreed about the lawfulness of the product. If the FDA is the umpire and is calling the balls and strikes on what is considered a lawful product, how is it that a company can stall the FDA by a continued dispute on lawfulness when lives are at stake?
17. Is there any initiative at FDA to reduce the enforcement delays after sending a warning letter? If so, what are they?

The Honorable Michael C. Burgess

1. Technology and data are revolutionizing many businesses and markets throughout our society and economy, but in order to take advantage of their power, we need to ensure that the data being shared is accurate. The HHS OIG report highlights that FDA's data collection and sharing has been hindering timely and effective food recalls. What steps is FDA taking to improve its data input and collection and to incentivize companies to share information in a timely manner?
2. The HHS OIG report outlines concerns surrounding the inaccuracy or incompleteness of information that companies provide to the FDA. Specifically, in a nut butter product case involving a *Salmonella* contamination, the firm was reluctant to provide FDA with information necessary to complete the Health Hazard Evaluation (HHE). To what extent can you engage with these companies to incentivize them to provide correct information in a timely manner? Are companies aware they are providing you with faulty information, or do you anticipate that their method of data collection is flawed?
3. Communication of recalls is important for the local public health officials on the ground investigating cases and making necessary interventions. How are recall notifications disseminated to local health officials? Is this data filtered to be applicable to the region/district or only nationwide recall notifications?
4. FDA Commissioner Gottlieb released a statement on December 26, 2017 stating that he wants FDA to "do even more to make sure that consumers have the information they need to avoid hazardous products that are the subject of recalls or seek assistance if they may have been exposed to a recall food product." What steps is FDA taking, or planning to take, to ensure adequate communication with and awareness among consumers during a recall?

The Honorable Frank Pallone, Jr.

1. FDA is still in the process of implementing key provisions of FSMA through regulations, including a requirement that firms in certain instances have recall plans in place. In order to realize the full potential of FSMA as Congress intended, these regulations must be implemented and enforced without delay. When will these regulations be fully implemented and enforced?
2. What can be done to expedite the process of implementing and enforcing these regulations?
3. In 2016, FDA established the Strategic Coordinated Oversight of Recall Execution (SCORE) initiative. Mr. Stearn's testimony indicated that SCORE is comprised of FDA senior leaders who make decisions during particularly complex or unusual food recall cases. How many recalls has the SCORE initiative handled, and what was the nature of these recalls (including the recall classification)?
4. Mr. Stearn's testimony indicated that one of the changes FDA has implemented since the OIG review was a new monthly monitoring system that indicates when a recall appears to be going slowly. What steps does FDA take when it determines that a recall is going slowly?

